

THE FEDERAL MEAT INSPECTION PROGRAM

Y 4. AG 8/3: S. HRG. 103-728

The Federal Meat Inspection Program... ARINGS

BEFORE THE

SUBCOMMITTEE ON
AGRICULTURAL RESEARCH, CONSERVATION,
FORESTRY, AND GENERAL LEGISLATION

OF THE

COMMITTEE ON AGRICULTURE,
NUTRITION, AND FORESTRY
UNITED STATES SENATE

ONE HUNDRED THIRD CONGRESS

SECOND SESSION

ON

REVIEW ACTIVITIES OF THE FEDERAL MEAT INSPECTION PROGRAM;
REVIEW OF USDA'S "ZERO TOLERANCE" MEAT INSPECTION POLICY;
REVIEW OF THE ADMINISTRATION'S PROPOSED LEGISLATION ON
MEAT AND POULTRY INSPECTION

FEBRUARY 10, 1994, MAY 24, 1994, and AUGUST 12, 1994

Printed for the use of the
Committee on Agriculture, Nutrition, and Forestry



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U.S. HOUSE OF REPRESENTATIVES
OFFICE OF THE CLERK
MAR 11 1993
U.S. HOUSE OF REPRESENTATIVES
OFFICE OF THE CLERK

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REVIEW ACTIVITIES OF THE FEDERAL MEAT INSPECTION PROGRAM

THURSDAY, FEBRUARY 10, 1994

U.S. SENATE,
SUBCOMMITTEE ON AGRICULTURAL RESEARCH,
CONSERVATION, FORESTRY AND GENERAL LEGISLATION,
COMMITTEE ON AGRICULTURE, NUTRITION, AND FORESTRY,
Washington, DC.

The committee met, pursuant to notice, at 2:30 p.m., in room SD-562, Dirksen Senate Office Building, Hon. Thomas A. Daschle, Chairman of the subcommittee, presiding.

Present or submitting a statement: Senators Daschle, Craig, and Cochran.

STATEMENT OF HON. THOMAS A. DASCHLE, A U.S. SENATOR FROM SOUTH DAKOTA

Senator DASCHLE. The hearing will come to order.

One year ago, this subcommittee conducted a hearing in response to the outbreak of *E. coli* infection in four Western States. This illness was caused by contaminated ground beef sold in a fast-food chain. At least 45 children were hospitalized, and, tragically, four died.

I am very disturbed by the reports I see, continuously, about the safety of our food products. There is no excuse, in my opinion, not to do everything possible to prevent foodborne illnesses.

In last year's hearing, all witnesses, including Secretary of Agriculture Espy, agreed that the current meat inspection system in this country is outmoded and inadequate to address the problems that resulted in the *E. coli* outbreak. After less than 2 weeks in office, he outlined an ambitious two-track plan for meat and poultry safety reform. I commend the Secretary for his quick response and for his commitment to improving the safety of our Nation's meat supply.

We are here today, 1 year later, to find out exactly what has been done, what has not been done, and, most importantly, what still needs to be done to ensure that our food supply is safe.

Today, we are examining the problems associated with meat. In the near future, I intend to hold a similar hearing regarding poultry. I would hope that somehow we can overcome the jurisdictional issues to address the problems with seafood as well.

Before we start, I want to make everyone aware that I intend to introduce legislation to give the Federal Government agencies, in charge of food safety, the necessary tools to carry out their mission. It is imperative that we provide the means for food inspectors to

prevent the abuses that I have seen and heard about, whether they occur in South Dakota or anywhere else in the country. We simply cannot tolerate an inspection system, that does not go the extra mile to guarantee consumers that the food they purchase is, beyond a reasonable doubt, safe.

My legislation will start by making the Food Safety and Inspection Service an independent agency within the Department of Agriculture. The reason for this is to ensure that the actions taken by this important agency are not overshadowed by the marketing or promotional activities of the same agency. The goal is to create one which is designated for food safety and nothing else.

I should add that the food safety inspection system at USDA is the most thorough and stringent of any food inspection system in the Federal Government. It does not rely on self-policing activities, such as are allowed by other agencies.

I strongly believe that USDA is the best equipped of all the Federal departments, and agencies, to ensure a safe food supply. However, to get the job done, we must arm USDA's inspection system with the proper tools to detect and prevent pathogen problems. For this reason, the legislation will give USDA the traceback authority it needs to identify and contain sources of contaminated meat. This authority will help prevent disease outbreaks if any contaminated products are detected.

I also intend to pursue legislation to ensure that the meat and poultry products we import are subject to the same scrutiny as our domestic supply. In this regard, we need to strengthen obvious weaknesses in our inspection procedures at the ports of entry.

But we really cannot stop there. We also need to address all issues necessary to ensure safe food. For this reason, I hope that today we will hear some positive, constructive suggestions on what we can do to ensure that our food is safe.

We will not tolerate or ignore the consequences of contaminated food. When children die, and an estimated 30 million Americans get sick each year from our food, it is time to take action. If that means more inspectors and better detection, then let's do it. If it requires more research, then let's fund it. If it requires modifications in production, processing, storage, or preparation, then let's get the job done.

I should add that an effective food safety system is not only designed to protect the interests of consumers, it is just as important to protect farmers and ranchers who produce the food. If food is not safe, consumers lose confidence, and that impacts on the demand for farmers' products.

We are currently involved in one of the biggest debates in some time regarding the future of our health care system. One of the most critical aspects of health care is the fact that prevention is in everyone's best interest.

If millions of people in the United States get sick annually from foodborne bacteria, then we have to act to prevent this problem. The cost of treatment is enormous. We spend approximately \$1 billion a year to inspect food, which is pretty small, when you consider that we spend over 14 percent of our gross national product on health care. Let's prevent the problem, not treat it.

Nothing we can do now will bring back children who have died. However, what we can do is change the system to prevent other outbreaks from occurring. I welcome the suggestions of our panel this afternoon.

I am pleased to welcome Ms. Patricia Jensen, the Acting Assistant Secretary for Marketing and Inspection Services. I would also like to welcome four witnesses who will present the views of consumers, industry, public health, and producers on this issue: Ms. Carol Tucker Foreman of the Safe Food Coalition; Mr. J. Patrick Boyle of the American Meat Institute; Dr. Glenn Morris of the University of Maryland School of Medicine; and Dr. Edward Johnson of the National Cattlemen's Association. I thank all of them for their willingness to testify this afternoon.

The issue of food safety is charged, and many groups representing a number of diverse interests wish to provide input. For this reason, I have solicited written testimony from over 30 organizations with an interest in meat safety. I appreciate the efforts of all those who presented written testimony, and I would request that the record remain open for 2 weeks to allow us to receive remaining written testimony.

I also have had the good fortune to serve with our ranking Member on this subcommittee for some time now and would welcome his remarks as we begin this hearing this afternoon.

STATEMENT OF HON. LARRY E. CRAIG, A U.S. SENATOR FROM IDAHO

Senator CRAIG. Mr. Chairman, it looks like we are going to be in a relatively brief session this afternoon based on some floor votes that have just been announced. I will keep my remarks short. Let me congratulate you on your responsiveness a year ago as we dealt with this issue after some very tragic situations occurred and there were lives lost. It was clearly an issue that demanded our quick response. You have appropriately outlined that response, the response of the then new Secretary of Agriculture, Mike Espy, and what has transpired since that date.

I also last night, as many of you may have, watched a television program on this subject that placed a variety of arguments and propositions before the American public. The one thing I think it is important for me to say, as we move through this issue, is that America today has the safest food supply in the world and the highest quality food supply. I do not think we can argue that it is unsafe in a general sense. It is also clearly obvious to us that there are problems. There are problems that demand a new view of our ability and the ability of the supplier, the processor, the producer, and the ultimate preparer of the food, or at least a review of what we have been doing.

I am always amazed—and we find ourselves falling into that trap, Mr. Chairman—that once we pass a law and the executive branch implements it and we move 20 years down the road, we very seldom look back or keep a constant review of where we have been or what we are doing. We do know that what we are engaged in, the supply of food to the American consumer, is not a static environment, but is a modern and dynamic environment. To suggest a retrenchment back toward a system of inspection that has existed

for 30 or 35 years—that is the way it was done so that is the way it ought to be done; we ought to continue to do it with just more of the same, because that is the way we have been doing it—I think begs the question.

“The question is, ‘Are there newer and better techniques? Can they be done in a more successful way that will result in a safer food supply, adding to a food supply that is already relatively safe?’” Techniques that also suggest an emphasis on the whole, and by that I mean actually monitoring from the producer of the animal to the preparer of that animal product.

Those are the kinds of issues that must be addressed. Any proposal that you or I or anyone else could come up with, that attempts to ignore any of those aspects, in my opinion, does not address this issue properly.

As you will remember, I took issue with the fact that the preparer of those hamburgers simply did not have the appropriate grill temperature. Well, we believe that was probably the case. We also know that the *E. coli* bacteria was in the meat upon arrival. That is why we are here, that is why we have looked, that is why the Secretary has responded. It is very important today that we listen closely to those who are now out in the industry working extra hard to see if there are different ways or newer ways of resolving this issue.

It is my pleasure to have with us this afternoon Dr. Ed Johnson of Parma, Idaho. I have known Dr. Johnson for a good number of years. He is a dedicated, responsible practitioner of veterinary medicine, along with being a provider of quality foods through a variety of interests. He is also part of the Meat Inspection Subcommittee of the National Cattlemen's Association.

I had the privilege of visiting with him earlier today. I found that some of the things that are going on now, very aggressively funded by an industry who demands that their product be safe and be of high quality for the consumer, are attempting to take a leap forward. We are talking about some new ideas and approaches to which I think we must be open-minded and not just, as I said earlier, more of the same is better. I think what we have to understand is that maybe in this modern society we can tackle this age-old problem just a little better than we have in the past.

Thank you, Mr. Chairman.

Senator DASCHLE. Thank you, Senator Craig.

Let me make an announcement as a result of the reference Senator Craig made to the vote. We have a vote that begins at 3:15, and I am told that there will be five votes in succession following the initial vote, which means that we are going to be over there for a while.

I would like to suggest for that reason that we do something we normally do not like to do in this subcommittee, and that is put a limit on time for each of the presenters just to be sure we get through all of the presentations prior to that vote. I know some witnesses may not be able to stay until we come back, so we will work under those rules and go from left to right, if we can, and call upon Ms. Jensen for her comments initially.

[The prepared statement of Senator Cochran follows:]

STATEMENT OF SENATOR THAD COCHRAN

Mr. Chairman, I would like to commend you for holding this very important hearing to address the safety of our Nation's meat products. The U.S. meat industry accounts for over \$60 billion in product sales, with annual U.S. per capita consumption of over 223 pounds. U.S. consumers deserve the assurance that the meat products they eat are safe and wholesome.

In January of 1993, the highly publicized incident of improperly cooked contaminated hamburger meat, which led to illness and death, emphasized the need for improvements in our outdated methods of inspection which have essentially been the same since the passage of the Meat Inspection Act in 1907.

Here we are 87 years after the passage of the first mandatory meat inspection legislation, with very little change in the way our meat and poultry products are inspected. We still rely on an organoleptic inspection system which is based on sight, smell and touch to ensure that our meat and poultry products are unadulterated, safe and wholesome. The current inspection system is not adequate to detect and control the problems that most concern consumers today.

I am pleased with the responsiveness that Secretary Espy demonstrated last year in the *E. coli* outbreak and his willingness to pursue efforts to modernize the meat and poultry inspection system. While this outbreak has directed large amounts of attention to the need to reform our inspection system, we must take every step to ensure that this type of situation never occurs again. In 1985, the National Academy of Science evaluated the inspection systems for our Nation's food supply. The Academy concluded that the current inspection programs had largely achieved their original objectives of cleaning up plants and detecting visible lesions and diseases so that only healthy animals entered the food supply. The Academy also concluded that the Hazard Analysis and Critical Control Point (HACCP) system provides a more specific and critical approach to the control of microbiological hazards in foods than that provided by traditional inspection and quality control approaches.

The Government, producers, processors, food handlers, and consumers all share in the responsibility of ensuring the safety of our meat supply. By nature, all raw meat contains bacteria, and if not properly handled and prepared, serious illness may occur. The way to improve the safety of our meat products is in preventing problems before they develop by using safe, modern techniques of production, processing and distribution. Our current inspection system, which focuses only on the visual inspection of the product, fails to detect, or even reduce, microbial contamination. Therefore, the Department's decision to hire more meat inspectors will not result in better detection of microbial contamination and is viewed as a band-aid approach to solving a more pressing problem. In fact, it is viewed by many that the Food Inspectors' Union is a defender of the *status quo*, and is opposed to efforts to move beyond visual inspection because some of its members may lose their jobs.

The ideal solution to meat safety standards would be the total elimination of harmful microbial contamination in our meat supply. Sound, scientific research is essential in developing methods to detect, reduce, and ultimately eliminate, this contamination.

Our citizens have the right to be assured that the Federally inspected meat products, they consume, are safe and wholesome. As we address this serious issue, I plan to work with the Administration, industry leaders, and consumer groups to achieve this goal. I look forward to the testimony of our witnesses.

STATEMENT OF PATRICIA JENSEN, ACTING ASSISTANT SECRETARY, MARKETING AND INSPECTION SERVICES, UNITED STATES DEPARTMENT OF AGRICULTURE

Ms. JENSEN. Thank you, Mr. Chairman. I have a prepared formal testimony in writing that I would like to have submitted for the record.

Senator DASCHLE. Without objection.

Ms. JENSEN. Thank you.

Mr. Chairman, Members of the subcommittee, I do appreciate very much having this opportunity to discuss meat and poultry inspection, and safety activities of the U.S. Department of Agriculture. As you recall, Secretary Espy appeared before you last year, about this same time, to express his deep concern for the families affected by the devastating outbreak of *E. coli* 0157:H7 in

Washington State, and to assure this subcommittee that he would make food safety a top priority at USDA under his tenure. His commitment continues.

I have just returned from Washington State, and like the Secretary the year before, I also testified before a State Senate committee about the Washington State *E. coli* outbreak. I also met with several of the families whose children became ill or died during last year's outbreak. It is heartbreaking to hear these families' stories. It is because of these families that Secretary Espy and I are prioritizing initiatives that we hope will lead us to the prevention of such tragedies.

For your information, President Clinton, too, has also made improving meat and poultry inspection one of his highest priority investment initiatives.

While serving as Deputy Commissioner of Agriculture for the State of Minnesota in the late 1980's, we had a similar outbreak of *E. coli* 0157 that was linked to precooked hamburger patties. As a result of that outbreak, Minnesota developed a strong response mechanism to act quickly and aggressively in the future. That response included interagency cooperation, media advisories for public information, increased sampling and testing, improved State laboratory ability, cooperation with universities for research, communication with industry and the legislative committees, and dialogue with Federal agencies.

Secretary Espy and I want to be sure that that same type of comprehensive response occurs here in the Federal Government. Since the day Secretary Espy was sworn in last January, he has moved quickly and aggressively to revamp the meat and poultry inspection system.

As you requested in your letter of invitation, I will discuss the activities that have taken place in the year since the outbreak, as well as future plans.

Today, we are making progress as we seek ways to better protect consumers from foodborne pathogens. Last year, Secretary Espy laid out a strategic pathogen reduction plan that included improvements in education, regulations, testing, enforcement, research, and in new technologies. His plan addressed each step from the farm-to-the-table continuum, if you will. Right now we have over 70 initiatives under way, and I would like to submit for the record charts¹ we have prepared for each one of these initiatives and to discuss them with you when we have more time available.

Ms. JENSEN. A critical part of the Pathogen Reduction Program is consumer education. On November 4, we published our proposed rule for mandatory safe handling labels on raw and partially cooked meat, and poultry products. Although a lawsuit delayed earlier implementation of the labels, we remain fully committed to this initiative and expect to publish a final rule in the very near future.

A September teleconference was held by FSIS and FDA for State health officials to discuss the *E. coli* outbreaks and the steps necessary to prevent future foodborne illnesses. Public service announcements have been sent to over 1,000 radio stations around

¹The charts that Ms. Jensen makes reference to are retained in Committee files.

the country. One of the families tragically affected by the Washington State outbreak participated with us in this effort.

USDA agencies are working together to distribute food safety information through the Food and Nutrition Service's Child Care Food Program, which reaches nearly one-quarter of the Nation's children in day-care and Head Start. We are targeting efforts to educate young mothers and food handlers in restaurants and in hospitals, in nursing homes, in day-care centers and homeless shelters. Education is critical for those serving the most vulnerable of our population.

We recently completed our first nation-wide microbiological baseline survey on steers and heifers, and we are instituting other microbiological baseline surveys for bulls and cows, poultry and swine, and they will all begin very soon.

Implementation of micro testing into preoperational sanitation inspection was initiated in November of 1993. An announcement in the FEDERAL REGISTER spelled out the criteria for rapid microbiological tests that will be of use to the Food Safety and Inspection Service. Rapid tests to detect and count bacterial pathogens are basic to learning more about pathogens and enforcing the rules on bacterial contamination.

The Pathogen Reduction Program includes a preharvest food safety focus. Pre-harvest food safety deals with the beginning of the food chain, on the farm where the meat and poultry production actually begins, and continues through the transportation all the way to the slaughterhouse. Pre-harvest food safety activities are primarily the responsibility of the Department's Animal and Plant Health Inspection Service—APHIS. APHIS is uniquely qualified for preharvest food safety work because of its work in animal health, its traceback capability, and a longstanding relationship with State animal health and public health officials.

In February of 1993, Secretary Espy directed FSIS to aggressively enforce procedures to ensure that all fecal, ingesta, and milk contamination is removed from beef carcasses. Unannounced reviews late last spring to assess the implementation of the zero-fecal program at 90 large plants revealed problems requiring immediate action. Results of a review of 26 turkey plants operating under the New Turkey Inspection System were released last Friday, and seven plants were notified of a need for stronger emphasis and quality control while three had serious findings involving products ready for shipment.

The newly created Review and Assessment Office has completed over 200 of 1,000 unannounced plant reviews throughout the United States, and we have 275 Federally inspected plants now under Progressive Enforcement Action. That compares to just 90 when Secretary Espy took office 1 year ago, and is three times the number we had last year.

We have hired 400 inspectors this year and plan to hire an additional 200 in 1994. The Department is in the process of developing a legislative proposal that will provide the Secretary with necessary statutory authority to ensure that there will be no gaps in our ability to address food safety.

In September of 1993, a new regulation—

Senator DASCHLE. If I could ask you to summarize, Ms. Jensen, that would be great.

Ms. JENSEN. Certainly. In summary, Mr. Chairman, Secretary Espy has pledged that we will have a science-based inspection system, that we will have more focus on public health, that we will have tougher enforcement, and improved consumer education. That is the direction we are heading now, and the direction we will head in the future. I want to take this opportunity to thank the Members of this subcommittee for your dedication to this issue, and to assure you that we, in USDA, do stand ready to work with you. We would like to form a partnership with Congress, with the States, with local governments, with industry, parents, health officials, scientists, consumers, producers, and everyone else who is wanting to come to the table.

Thank you again, Mr. Chairman.

Senator DASCHLE. Thank you. I want to emphasize that the entire statements of each of our witnesses will be made part of the record, and I thank you for your cooperation.

Ms. Foreman?

STATEMENT OF CAROL TUCKER FOREMAN, COORDINATOR, SAFE FOOD COALITION, AND PRESIDENT, FOREMAN AND HEIDEPRIEM, INC., WASHINGTON, DC.

Ms. FOREMAN. Thank you. I would like to make that request as well.

Senator DASCHLE. Could you pull the microphone up to you?

Ms. FOREMAN. I actually will surprise everybody by saying that I am in agreement with much of Assistant Secretary Jensen's summary statement. As recently as last November, the Safe Food Coalition was very critical of USDA and the Clinton administration for the progress it had made in improving meat and poultry inspection.

Although the progress has been slow, painful, and not completely successful, we do see some important achievements. We commend the Administration, first, for recommending in the National Performance Review that meat and poultry be moved out of the Department of Agriculture and put into a public health agency; for hiring additional inspectors; for increasing the number of unannounced reviews; for requiring that meat carcasses be free from fecal contamination in the plant. We hope the Secretary will fulfill the second-half of that pledge and extend the zero-fecal contamination policy to poultry.

We commend the Administration for really working hard to get safe handling labels on meat and poultry products. If it finally happens, this is going to be a major accomplishment. We agree that consumers have a role to play in protecting themselves. They have to have information in order to do it, and the best place to have it is on the package.

Twenty years have gone by since the Federal court ruled in *APHA vs. Butz* that the Department of Agriculture has the authority to put these kinds of labels on meat and poultry, and it looks like Secretary Espy is finally going to make it happen.

There has been less progress, in our view, on developing rapid on-line tests to detect bacterial contamination. Although the Department is now beginning to take some steps in that direction,

there is really not a focused program that has set goals and timetables for getting those tests developed and getting them implemented in the plants where they belong.

We are also very disappointed at the lack of progress on traceback legislation or regulations. It has been a year. The Department does not have a regulation, and it has not been able to get itself together to send a proposal up to the Congress to act on. That is not acceptable.

USDA has also failed to establish limits on the amount of bacteria that can contaminate raw meat and poultry. That contamination, as we know, puts every consumer in jeopardy of foodborne illness. It also makes a mockery of the seal that appears on packages of meat and poultry that say that the product has been inspected by the U.S. Government and declared wholesome. That label, as it appears today, is frequently just not true, and it should not be there.

I would like to address the rest of my time to the proposed Hazard Analysis and Critical Control Point System, known as HACCP. We think that it has to address the problem of bacterial contamination. We believe that HACCP can be a very important step in preventing problems in the plant and, therefore, in contributing to improved safety.

However, it is a major departure from the way we have done things in the past. It will be very expensive. We believe that the public has a right to have this tested in a number of ways and proved to be effective, before the Government gallops down the road, and grabs it up.

Before it is adopted by the Government, we would like to see empirical evidence from neutral third-party sources that says meat and poultry that go through a plant with a USDA-approved HACCP system is cleaner, safer, and less likely to cause foodborne illness than meat and poultry going through a plant that does not have a HACCP system. We do not think that is an unreasonable expectation. We do not see how the Government can justify mandating such a system unless it can provide that evidence.

HACCP is a good manufacturing procedure. It is not, and really never was, designed to be an inspection system. Even the best HACCP system will not safeguard the public against people who set out to cheat. If it is going to be used as a government regulatory program, it has to have provisions built in that will do that. Therefore, if HACCP is adopted by the Government as part of an inspection system, it has to include regulatory safeguards, such as the ability to impose civil penalties, open records, and protect whistle-blowers.

Unless HACCP can be shown to improve safety and has controls to prevent cheating, then it will not be anything but an industry honor system in which each plant sets its own standards and performs its own inspections, with inspectors paid by the company. That will not restore the public's confidence in the American meat system.

Americans do expect their food to be safe. Despite that, several million people each year become ill, and several thousand die from bacterial foodborne illness. Our Government and our industry say that it is the safest food system in the world. It may be, but it is

not safe enough, as witness—those people who have gotten sick and died from these problems over the past 10 years.

Thank you.

Senator DASCHLE. Thank you, Ms. Foreman.

I have already announced that Patrick Boyle, the president and chief executive of the American Meat Institute, is our witness. I do not know if I mentioned that he is accompanied today by Dr. James Marsden, who is the vice president for scientific affairs. Gentlemen, welcome—both of you.

STATEMENT OF J. PATRICK BOYLE, PRESIDENT AND CEO, AMERICAN MEAT INSTITUTE; ACCOMPANIED BY JAMES L. MARSDEN, VICE PRESIDENT FOR SCIENTIFIC AND TECHNICAL AFFAIRS, AMERICAN MEAT INSTITUTE, ARLINGTON, VIRGINIA

Mr. BOYLE. Thank you very much, Mr. Chairman, Senator Craig. We are glad to be here again this year, as we were last year. During the past 12 months, AMI and its member companies have pursued a number of initiatives to prevent foodborne illness, to promote food safety research and education, both within the industry, within government, and amongst consumers, and to reform the meat and poultry inspection system.

In the past year alone, I believe we have made noteworthy progress, and I would like to highlight some of that for you here today.

The AMI Foundation, created just 18 months ago, has raised nearly \$4 million, some of it from beef producers through the check-off program, some of it from private companies, to find new ways to prevent or destroy harmful bacteria in raw meats before the food even leaves our plants. Our research has confirmed, for example, that low-level irradiation and acidic carcass mists dramatically reduce bacteria on meat. I do have a chart here that will visually convey more dramatically and simplistically than I could by taking up additional time verbally.

On the top part, you see an *E. coli* bacteria, taken by swab from an intentionally infected beef carcass. The lower picture is that same sample after it has been treated with low-dose irradiation, actually a level one-half that FDA has approved for use in poultry a number of years ago. So the technologies are there, and we are discovering more and more of them every day.

For example, we are now researching the antimicrobial effects of carcass rinses, electronic pasteurization, pulse-light technology where you flash lights at the meat to reduce pathogens, and alkaline carcass mists.

In addition, our foundation has contributed to and is working with the Lois Joy Galler Foundation to find a cure for hemolytic uremic syndrome, a devastating disease that results from *E. coli* 0157:H7. If we could detect and treat better this disease, we would be able to prevent the severe, and sometimes life-threatening, complications to children.

Our foundation at AMI is aggressively training food safety specialists from meat and poultry plants to use a state-of-the-art processing control system called HACCP, which Ms. Foreman and the Assistant Secretary referred to earlier. We are sponsoring five

courses this year with universities around the country addressing beef, pork, and poultry processing techniques. We have been doing this for a number of years already. We have trained about 500 participants in these conferences in the past.

Interestingly enough, Mr. Chairman, the single organization that has been the largest participant in the AMI HACCP training programs has been the Food Safety and Inspection Service, and we think that is a positive development because we have an educational challenge both within the Inspection Service and within the industry we represent.

This HACCP system has been endorsed by neutral, unbiased, third-party observers and sources like the National Academy of Sciences and the Food and Drug Administration. For example, as you know, FDA has proposed rulemaking to mandate HACCP for seafood.

Today, AMI has formally petitioned Secretary Espy to initiate similar rulemaking to mandate HACCP programs in all meat and poultry plants in the United States, and I would like to submit for the record a copy of the letter², that I sent to Secretary Espy today, urging him to go forward immediately, and make this proven system a mandatory part of our Nation's meat and poultry inspection requirements.

AMI has also supported the safe food handling labels in the past year for raw meat and poultry products, and, indeed, 6 months before the Secretary even promulgated an interim regulation in August, we had developed and distributed literally millions of safe food handling brochures for ground meat and ground poultry, in cooperation with food retailers and food service establishments throughout the country. If you work your way through the supermarkets, as I do, as I make my way across the country, I am repeatedly pleased to find these brochures available in many stores throughout our Nation.

Although we have taken a number of steps within industry in the last 12 months, we think we need less talk at this point, Mr. Chairman. We need more action such as a mandatory regulation for HACCP from the Department of Agriculture.

In addition to supporting and now formally requesting such a mandatory regulation, AMI has developed a comprehensive model of what a 21st century farm-to-table food safety inspection system should look like. In the next few moments, I would like to share just some of the key elements with you that are discussed in greater detail in my formal testimony that I have submitted for the record.

First, the primary goal: to prevent human health hazards from farm to table—a goal supported not only by AMI, but by two separate 1985 reports from the National Academy of Sciences. We agree with NAS—and I quote—"The most effective way is to control hazards at their point of entry into the food chain." In other words, we should start our inspection oversight on the farm, rather than the packing house door. It should not end at the processing door as the product goes into further distribution, but it should extend beyond that to the table.

² See Appendix I, page 113.

The livestock and poultry farms of the future will use HACCP principles to design, monitor, and adjust their animal husbandry practices. Many producers are already using such sophisticated techniques. Producers will keep records on both the source and the destination of their animals to facilitate the traceback that Ms. Foreman mentioned in her earlier testimony similar to the record-keeping, Mr. Chairman, that I believe, you envision in your legislation on this issue. When those animals arrive at packing plants, producers will have already used immunological tests to identify those that may pose problems of public health concern, and our members will know which ones they are and provide them with greater scrutiny or different treatment to ensure that they do not enter the food chain further.

The packing plants of the future will be required by government to operate using HACCP principles. The packing and processing plants will be required to employ a certified HACCP technician in every one of their plants. There would be recognized HACCP training and certification programs, and there would be independent audits to ensure that industry is complying with the mandatory requirements set forth by the Government.

Once the meat and poultry products leave our plants, there is still need for vigilant control. Ninety-seven percent of the foodborne illnesses in America, according to the Centers for Disease Control, are traced to points in the food distribution process after they have left the food plants. So, Mr. Craig, as you have indicated, we need to go beyond the focus that we have had for almost 100 years since 1906 when this system began.

Then, finally, Mr. Chairman, we need a government program that embraces the HACCP principles that is based upon science, based upon objective risk assessment, and allocates its resources to the sources of the problem so that we can address the food safety concerns of the 1990's. Thank you very much.

Senator DASCHLE. Thank you, Mr. Boyle.

Dr. Morris?

Senator CRAIG. Mr. Chairman, before you start, let me ask unanimous consent. Senator Dole asked if I would submit this gentleman's testimony for the record, Dr. Jerry Gillespie, Kansas State University, representing Food Animal Production Medicine Consortium.

Senator DASCHLE. Without objection, it will be made part of the record.

Senator DASCHLE. Dr. Morris?

STATEMENT OF J. GLENN MORRIS, JR., M.D., PROFESSOR OF MEDICINE, PROFESSOR OF EPIDEMIOLOGY AND PREVENTIVE MEDICINE, UNIVERSITY OF MARYLAND SCHOOL OF MEDICINE, BALTIMORE, MARYLAND

Dr. MORRIS. Thank you. It is a pleasure to be here today. I am coming from perhaps a little different direction than some of your other speakers—

Senator DASCHLE. Could you take the microphone a little bit closer? Thank you.

Dr. MORRIS. I am perhaps coming from a somewhat different direction than some of your speakers in that I am not here as a

member of a specific interest group. I am a physician, epidemiologist, and a scientist. I have served on three National Academy of Sciences expert panels which have dealt with problems of food inspection, and I am currently a member of the National Advisory Committee on Microbial Criteria for Food.

What I would like to do today is briefly talk about some of the public health implications of the problems we have with food inspection. I am not going to go into a great deal of detail regarding the most recent surveillance data from the CDC. I believe those data have been entered into the record from the CDC. However, I would note that their data show that within the past year there have been 17 outbreaks due to *E. coli* 0157:H7 as compared with 25 outbreaks during the past 11 years. This does seem to be a clear increase. Part of this, of course, is due to the attention that the 0157:H7 cases have received due to the outbreak in Washington State.

Nonetheless, I think what this says is that we do, indeed, have a problem. It is not going away, and it is something that we are going to have to deal with if we are going to try to get control of this disease. I would also point out that it is likely that these 17 outbreaks are only the tip of the iceberg. There are probably a number of other cases which are not diagnosed either because the patient does not go to see a physician, because the physician does not obtain appropriate cultures, or because the laboratory that is examining the stool samples does not have the technology to identify this organism. This is not something that will be picked up in a routine stool culture. The laboratory has to know what it is looking for and has to have the right technology to do it.

I will not go that much into the actual clinical syndrome. As you are all aware, it can be a devastating disease. One particularly severe outbreak occurred in a nursing home where 22 percent of the patients, infected with this organism, developed hemolytic uremic syndrome; 90 percent of those died. This is an organism that it would be nice to reduce the incidence of.

Unfortunately, as this committee is aware, our current meat inspection system is a relic of the early part of this century. It is based on organoleptic inspection—simply looking and feeling. It does not address issues relating to bacterial contamination of meat. Expert committees of the National Academy of Sciences and the GAO have looked at the current inspection system, in depth, in a series of studies, and a common theme, throughout these studies, is the idea that the current inspection system needs to be replaced with a scientific, risk-based inspection system that is targeted toward human disease and disease prevention. The 0157 outbreaks highlight the need for this type of approach.

USDA has clearly expressed a willingness to move toward implementation of such a system. However, it is not an easy process, and I will have to say, looking at it from the outside, that the progress appears to be somewhat glacial.

Just to briefly summarize, what exactly is necessary for implementation of a risk-based inspection system? First of all, we need data. Development of a rational risk management program is dependent on having the data necessary for risk assessment. A common complaint throughout all of the reports that have come from

the National Academy has been the total lack of adequate data to perform risk assessment. Data needs include epidemiologic data on human illness to identify foodborne hazards and characterize risk, and microbiologic data to assess the probability of exposure to these hazards.

In looking specifically at the 0157:H7 problem, there are some very interesting, innovative studies being done, particularly looking at the ecology of the organism. However, there has not been a concerted research effort made to try to identify where the organism is coming from, what the risk factors are, nor have efforts been made to take advantage of outbreaks or other situations in which it might be possible to try to better determine how to limit risk of transmission of this organism.

Second, there is a need for a structure around which to build such an inspection system. HACCP is the magic word. Everybody is saying it today. I think HACCP is a reasonable system around which to build this type of inspection system.

However, I would point out that HACCP is simply a quality control system. There is nothing magic about HACCP. You could use HACCP to look at refrigerators. It does not do anything in and of itself to provide safe meat. The key to a HACCP system is the data on which it is based. A HACCP system which is based on poor data is a lousy system. So, consequently, I too would urge caution in moving rapidly toward HACCP until we, indeed, know what we are doing, and we have the appropriate data to make certain that the HACCP system which we are designing, is based on a rational scientific basis.

Third, there is a need for appropriate technology. In microbiology, this translates into development of rapid diagnostic techniques. There are now methods which will allow identification of *E. coli* 0157:H7 within a matter of hours. It is this type of on-line, rapid diagnostics which are needed to make HACCP work. You have got to be able to have immediate feedback. You have got to be able to sample the product and know where you are running into problems. Unfortunately, USDA has not aggressively pursued these rapid diagnostics. Actually, I sat and talked with Dr. Cross for a while about some of these, and his comment was that it could not be done because of regulations, the difficulties involved in introduction of new technology, and similar constraints.

Fourth, there is a need for an innovative, multidisciplinary team to direct such changes. What the National Academy has proposed is a very radical reshaping of the inspection policy. The National Academy and GAO reports have repeatedly taken USDA to task for failure to follow academy recommendations, raising serious questions about whether the Agency has the initiative or skills to implement such a system. Events since the 0157:H7 outbreak of a year ago really have not provided any reassurance that this has changed. There is the Pathogen Reduction Program. It looks nice, fills up a lot of paper, a lot of things in here that nobody in his right mind could disagree with. There is really—the substantive components of this are missing. There is really nothing innovative or that substantive about what is included in this report.

It is a good start. I have no doubt that the USDA is moving in the right direction, but they are moving very slowly. In their de-

fense, I am well aware that USDA has been shackled by current regulations. There is clearly a need for new enabling legislation which will permit food safety and food inspection to move into the 21st century. Unfortunately, again, this legislation has not been aggressively pursued.

To summarize, 0157:H7 disease is still with us. There is no indication it is going to disappear any time in the near future. What we need for meat inspection is a scientific, risk-based inspection system for meat and meat products. There have been voluminous studies dealing with this issue. I have wasted many months sitting on committees. I have been through this again, and again, I do not want another report; I do not want another study—I want to see something done. You know, the studies are there—lots of studies—and they all say the same thing.

If we are to address the 0157:H7 issue in a meaningful way, we need to have a major restructuring of food inspection systems. This needs to be done by an innovative, multidisciplinary team, backed by appropriate enabling legislation. I would urge the committee to move in this direction.

Thank you.

Senator DASCHLE. Thank you, Dr. Morris.

Finally, Dr. Johnson?

STATEMENT OF EDWARD JOHNSON, D.V.M., CHAIRMAN, MEAT INSPECTION SUBCOMMITTEE, NATIONAL CATTLEMEN'S ASSOCIATION, PARMA, IDAHO

Dr. JOHNSON. Thank you, Mr. Chairman. I appreciate the opportunity to be here today and to testify. I appreciate Mr. Craig introducing me at the start of this hearing.

In a way of background, I am a veterinarian. I own and operate a private contract research facility. I am also in the commercial cattle-feeding business and in the cow/calf business.

Relative to the issue of 0157, I have a great deal of personal interest as well as being a spokesman for the National Cattlemen's Association. Our daughter is a nurse, and she was on the floor at Children's Hospital in Seattle when the *E. coli* outbreak took place a year ago. After many conversations with her, I do not ever want to see a child infected or any person infected with that horrible organism coming from my ranch or from my feedlot. So this was a very personal issue with me.

As an industry and a spokesman for the National Cattlemen's Association, we support a scientifically based HACCP farm-to-table approach to meat inspection that utilizes the principles of risk assessment, risk analysis, and innovative technological change. We believe the only way we will provide greater food safety is through a thorough scientific approach.

The current organoleptic system we have right now relative to feel, smell, and touch has been effective, as far as reducing contamination on beef carcasses, and reducing some of the cattle diseases, which it was primarily designed to do. It certainly does not go near far enough to meet the challenges we have with ubiquitous organisms, such as 0157:H7. We have got to move much, much further and much faster into a technological area to be able to address that problem.

The new system that comes about must be based on good scientific data and methodology. Good scientific data gathering and analysis basically follows HACCP's procedures. I can testify to that personally in our own research company. We work under that basis all the time, when we are testing new products that come under the auspices of the Food and Drug Administration that monitors our progress on a daily basis.

Your request at the hearing is: What has the industry been doing relative to food safety? In 1988, through the Meat Board, we requested our first studies on 0157 as we recognized this to be a very serious potential food safety issue. We requested epidemiologic studies in 1990. We have set up—throughout the National Cattlemen's Association—beef quality assurance programs, which are an information and education cooperative effort, with every major cattle-producing State. We have 41 States that now have quality assurance programs. Through this, we have a network by which we can work with APHIS or whatever other regulatory agent to help implement an on-farm inspection system.

We have—and I would like to submit it for the record—traceback studies³ that have been conducted by our industry relative to what our capability is to follow these animals from slaughter back to the farm or the feedlot of origin, if you would submit those, please.

Senator DASCHLE. Without objection.

Dr. JOHNSON. I have also my testimony, Mr. Chairman, that I have submitted in written form.

Senator DASCHLE. It will be made part of the record.

Dr. JOHNSON. In the last 4 years, the cattle industry, through our check-off dollars, has spent \$1.5 million to support research on 0157:H7. In 1994 alone, we have appropriated \$1.2 million to support research studies, and those studies are delineated in my written testimony.

There are a lot of things we do not know about 0157:H7 as it relates to the live animal, as it relates to how it is transmitted in the packing plant. There are a lot more questions than there are answers. There is a tremendous amount of need for research from the live animal side.

As a result of all of those questions, last September the beef industry appointed a special task force made up of producers, industry scientists, microbiologists, FSIS officials, public health epidemiologists, and quality assurance technologists. Since that time, we have been working diligently to gather all the data that is available, either written or in testimony, putting together a knowledge base so that hopefully we can come out with objective strategies for detection, control, and intervention of this organism.

As far as specific projects are concerned, at the NCA and the National Beef Board level this past year, studies have been initiated to look at an intervention step relative to pathogen reduction, reducing the microbial loads on beef carcasses, through a process of washing. This study, we have completed the first two phases of it, which are basically pilot studies to determine the best methodology through washing carcasses using different pressures, using different temperatures of water, and using possible additives such as

³ The traceback studies are retained in Committee files.

hydrogen peroxide or ozone. The result of those studies indicate that we have markedly reduced up to tenfold the level of bacterial contamination. The next phase is to take those studies into the field. We have contracted with five different meatpacking companies, and three slaughter plants, and two cow-slaughter plants, and five universities to obtain the data, and analyze it. If those studies are as effective as our preliminary data, we believe that we have a very meaningful means by which we can reduce the level of pathogens in beef carcasses.

In conclusion, I would like to say, as a cattle producer, that we support the professional staff of FSIS and their objectives to modernize, and improve the meat and poultry inspection system. As a cattle feeder, producer, and member of NCA, I will continue to commit my resources to resolve food safety concerns on the farm. I have additional data that we would like to submit, two of which are the results from our studies on the spray system, another of which involves the monetary expenditures that the industry is putting forward⁴.

Dr. JOHNSON. In conclusion, I hope that my testimony today, and additional written information I have submitted, will be included as part of the official record.

Thank you.

Senator DASCHLE. Thank you, Dr. Johnson, and I thank all of you for your cooperation in accommodating our schedule.

We have a very diverse panel, and let me just ask if there is a consensus among the diversity represented about this question. Can we assure the American people that they have more reason to be confident about the American meat inspection system today than they did 1 year ago? Ms. Jensen?

Ms. JENSEN. Mr. Chairman, thank you for letting me go first. I think the answer to that question is yes. I ponder the dilemma, though, of proving it because, in fact, we do not have consistent data, so that what you are asking us to say here today is definitely to give you an opinion. I think that because we have had better reporting and because we have emphasized safe food handling of food and we have done the educational piece, that has helped.

We have instituted, as I said, zero-fecal tolerance. I think that we would all agree that the likelihood of pathogens appearing at those spots is strong, and so we have emphasized that particular process and have added inspectors.

I would say, though, that I am not naive in this statement. There is a long way to go, and probably the agreement that you would get from all of us is that we all want to solve this problem.

Senator DASCHLE. I want to get to that, but let me just quickly ask, because we are very short on time: Does anybody disagree with that statement or wish to clarify what I understand to be a yes from all of you? Ms. Foreman?

Ms. FOREMAN. I think I would subscribe to it with the reservations that the Assistant Secretary made in her response.

Senator DASCHLE. OK.

Dr. Morris?

⁴The data referred to is retained in Committee files.

Dr. MORRIS. I am not sure. Again, I think I would push the idea that there are not necessarily the data to say one way or another. What I would emphasize is that the current inspection system does not address the issue. The current inspection system does nothing for microbial contamination, and so, in a way, the question really is not fair because right now we do not inspect meat for microbial contamination.

Senator DASCHLE. So with that caveat, you would say if we have a way with which to expand the inspection to microbial approaches as well, you would feel more confident. Is that a correct assessment?

Dr. MORRIS. That is correct. I am not certain there is any point to add more inspectors if they are doing the same thing. What we need to do is have an inspection system that looks specifically at microbial contamination, not one that watches the carcasses whiz by.

Senator DASCHLE. Mr. Boyle?

Mr. BOYLE. I would say yes for a number of reasons, but just to point out two—one, in the last 14 or 15 months, with USDA approval, we have been utilizing carcass rinses in our processing plants, and much like the research that Dr. Johnson mentioned, our experience has been a dramatic reduction in the bacterial load from prior levels that were relatively low to begin with. So there is that one demonstrable improvement in our operations.

Second, consumer education. I think we have a better understanding in this country today, as a result of events of the last 13 months, that each one of us as cooks in our kitchens are a critical control point, if you want to utilize HACCP terminology. We are critical control points, and we can ensure that the food that we are preparing and consuming is safe by handling and cooking, and storing it properly. I think that education has made the system better.

Senator DASCHLE. Yes, Dr. Johnson?

Dr. JOHNSON. I think, you know, we have certainly increased the awareness of the problem, but I do not think we have objective data out there to really demonstrate whether or not we have truly improved the safety aspect other than possibly from a greater awareness and a greater attention to detail.

Senator DASCHLE. In the interest of time, Senator Craig, let me turn to you for questions.

Senator CRAIG. Let me pursue further the proposition you proposed to the panel. In my conversations with Dr. Johnson, I think it is very important for you, Ms. Jensen, to grab hold of this if the studies prove out. One of the things you are doing right now—and I understand why you are doing it—because you have a system in place, and bodies to do certain kinds of things. Right now, in inspection and in the process on the line, there is a lot of trimming going on, as a result of certain kinds of impurities touching the carcass. That trimming results in time on the line. It results in temperature problems. It results in the loss of maybe 15 to 16 pounds of material, that then gets taken away from the producer, so there is a real cost factor; when the studies are showing that the sprays and the washings do not slow down the time, do not reduce temperatures, and may be reducing, dramatically, the pathogen that

we are concerned about. So we are moving, but the "question is, 'Can we move out of the rut?'"

Ms. JENSEN. I certainly hope so, Mr. Chairman, Mr. Craig. I am aware of some work being done now at Colorado State University on washing and trimming, and hopefully we will have more data in just the next few months. It certainly does seem to be going toward what you are saying, that the washing may actually turn out to be OK. We just need to make sure that the science is there to back up these statements, and we are very hopeful.

We have talked a lot about our inspectors and organoleptic inspection. We are training our inspectors in new scientific methods. We are not just sending out our inspectors to do exactly the same job they were doing last year. We are currently training all inspectors of meat plants about zero-fecal contamination. We are also training inspectors on microbiological testing of equipment, preoperational equipment, so that they can test for bacterial contaminants. We are showing them how to use swab tests on carcasses.

So I think that while it is true that this system is still much based on that old, old system, we are moving it along and providing that training for our inspectors, so that they will have the necessary tools, that they need, as we move ahead, and as we do the research and apply the science.

So on behalf of the inspectors, I would like you to know that they are receiving training, and, in fact, it is a science-based training.

Senator CRAIG. Mr. Boyle, did you wish to respond?

Mr. BOYLE. Just briefly, to follow up on the observation that you made, as well as the question that you raised. Your observation is absolutely correct. We have a zero-tolerance initiative as part of a pathogen reduction strategy. It is a laudable goal, but the reality is that while it has improved the physical characteristics of the carcasses, removing physical defects, it has not been designed to address the microbiological concerns that we all have because of the reason you mention. The carcasses are in the plants longer between when they enter the slaughterhouse floor and when they get into the coolers.

Senator CRAIG. Human touching alone.

Mr. BOYLE. Absolutely, Senator. We are hand trimming by knives, carcass after carcass after carcass. It improves the physical characteristic—a worthwhile goal. We think those standards should be made more uniform by USDA through good production practices and employed throughout the country to further improve the physical characteristics of these carcasses. It is not improving the microbial load even though it was offered as an opportunity to do so.

Rinsing, based upon the preliminary data that we have, would get us that more important objective, and we are hopeful the Department will look favorably upon those results and authorize us to do that in the very near future.

Senator DASCHLE. Ms. Foreman?

Ms. FOREMAN. Clearly, there is an assumption that if you trim away that fecal contamination, you have reduced the bacterial level. We do not have data to prove that—as we do not have it for a number of other things. Both Dr. Johnson and Mr. Boyle are so confident about the efficacy of these rinses, and I am not sure why under those circumstances they so vigorously oppose setting some

sort of guidelines for acceptable levels of bacterial contamination in these plants as part of inspection.

If they are so successful, why not trumpet it to the world? Why not say we set a standard and we can meet it?

Senator DASCHLE. We are going to have to adjourn. I want to note the presence of our colleague from Iowa, Senator Grassley, who is going to submit questions for the record.

Senator DASCHLE. We have but a few minutes left. I think given the circumstances it looks like we will have to be on the floor for about an hour-and-a-half. For that reason, I think we will submit what was going to be a fairly aggressive set of questions for the record and relieve you of the need to stay here an hour-and-a-half until we return.

Senator DASCHLE. Since this is a progress report on our efforts on inspection, I would invite any one of the panel members to give a letter grade on progress for the last year. Does anybody wish to venture out and give us a letter grade as a closing remark?

Senator CRAIG. Well, Mr. Chairman, let me suggest, because of this time factor, because there are a good many questions to be asked and I think we continue to move in that direction, let me thank you for this one. Let me suggest that somewhere down the road in a relatively immediate sense—and I guess that in the time of congressional activity could be 6 months—that we have an opportunity to come back to this issue and take another look with Ms. Jensen and the industry, as we move along, to make sure that we are in sync, and not in opposition, as we deal with this issue.

Senator DASCHLE. I think that is a good suggestion. Obviously we have just scratched the surface here. There are a lot of issues to cover, and I think given the fact that these issues are moving as quickly as they appear to be, it would be in our interest to regroup and rediscuss many of these issues, as it relates to the progress we intend to make, for the next 6 months.

Senator DASCHLE. With that, the hearing stands adjourned, and my thanks to all of you.

[Whereupon, at 3:29 p.m., the subcommittee was adjourned.]

APPENDIX I

PREPARED STATEMENTS

PATRICIA JENSEN

Mr. Chairman, and Members of the subcommittee, I appreciate having this opportunity to discuss the activities of the U.S. Department of Agriculture in response to last year's devastating outbreak of *E. coli* 0157:H7 in several Western States. As you may recall, Secretary Espy appeared before you last year, about this same time, to express his deep concern to the families affected by this outbreak, and to assure this subcommittee that he would make food safety a top priority at USDA under his tenure.

At the time of your hearing last year, Secretary Espy had just returned from Washington State, where he had met with the Governor and other State officials, and testified before a State Senate committee about the outbreak. His resolve to find solutions to this outbreak has only strengthened since then. President Clinton has also made improving meat and poultry inspection one of his highest priority investment initiatives.

I, too, have just returned from testifying before a Washington State Senate committee about meat and poultry inspection. The meeting that was even more important to me, however, was the meeting I had in Seattle with several of the families whose children became ill or died during last year's outbreak. It is heartbreaking to hear these families' stories. It is because of these families that Secretary Espy and I are pushing everyone at USDA to make the advancements that we hope will lead us to the prevention of these types of tragedies.

While serving as Deputy Commissioner of Agriculture for the State of Minnesota in the late 1980's, we had a similar outbreak of *E. coli* 0157:H7 that was linked to precooked hamburger patties. The Minnesota Departments of Health and Agriculture worked cooperatively to pinpoint the cause of the outbreak, and to inform the public.

As a result of this outbreak, Minnesota developed a strong response mechanism to act quickly and aggressively in future outbreaks. That response included inter-agency cooperation, media advisories for public information, increased sampling and testing, improved State laboratory ability, cooperation with universities for research, communication with industry, and with legislative committees, and dialogue with Federal agencies. Frankly, USDA did not cooperate in 1988.

Secretary Espy and I want to be sure that isn't the case now. Since the day Secretary Espy was sworn in last January, he has moved, quickly and aggressively, to revamp the meat and poultry inspection system.

There is still much to be learned about the bacteria *E. coli* 0157:H7. As we all know, *E. coli* outbreaks have continued to occur. Based on information USDA has received from the Centers for Disease Control (CDC), there were 16 reported outbreaks of *E. coli* 0157:H7 in 1993. In addition to those in Washington State, outbreaks have occurred in Illinois, North Carolina, Pennsylvania, Oregon (3), Connecticut, Montana, New Mexico, Massachusetts, California, Texas, and Maine. CDC has identified likely vehicles in many of the cases, and they range from ground beef, cantaloupe, mayonnaise, and raw milk to salad bars. As more States make reporting

of HUS and *E. coli* 0157:H7 mandatory, we will be hearing about more outbreaks. We are encouraging States to mandate the reporting of HUS and *E. coli* incidents.

As you requested in your letter of invitation, I would like to discuss the activities that have taken place in the year since the outbreak, as well as the activities planned, and those just getting underway. When Secretary Espy appeared before this subcommittee last year, he laid out a strategic pathogen reduction plan that included improvements in education, regulations, testing, enforcement, research, and persuading industry to adopt new technologies. His plan addressed each step in the farm-to-table continuum, where the potential for problems may be reduced.

Right now, we have over 70 initiatives underway. I would like to submit, for the record, charts⁵ we have prepared for each of these initiatives, and discuss some of them with you at this time.

Consumer Education

One critical part of the Pathogen Reduction Program is consumer education. Secretary Espy's call for mandatory safe handling labels on raw and partially cooked meat and poultry products, led to the publication of a proposed rule on November 4, 1993. These labels will remind consumers to handle and cook meat and poultry products properly, to ensure they are safe. As you know, a lawsuit filed by the National Grocers Association, the Texas Food Industry Association, the National/American Wholesale Grocers Association, and the International Food Service Distributors Association delayed earlier implementation of the labels. However, some segments of the food industry have responded positively to Secretary Espy's call by voluntarily supplying safe handling, and cooking instructions on their products. We are fully committed to this initiative, and we will continue to push until labels appear on all raw and partially cooked meat and poultry products. We expect to publish a final rule mandating safe handling labels in the very near future. In no way does this label, however, relieve USDA from its responsibility to improve the meat and poultry inspection system.

As part of the safe handling label initiative, the Food and Nutrition Service (FNS) has joined the Food Safety and Inspection Service (FSIS) in a campaign to spread the word about safe cooking and handling of meat and poultry to sites preparing meals with USDA donated commodities. For example, FNS is in the process of printing posters for homeless shelters and soup kitchens. As you may know, one of the *E. coli* 0157:H7 outbreaks late last year in Washington State involved a homeless shelter.

USDA has implemented a number of consumer education and training campaigns, including a program specially focused to involve local health communities and food preparers who serve the public. Two special target groups have been the population most at risk for foodborne disease—the elderly, and the very young. Cooperative efforts with the Food and Drug Administration (FDA), FSIS, USDA's Extension Service and others have also resulted in a more consistent, educational message reaching food preparers, and the general public.

USDA's Meat and Poultry Hotline received more than 130,000 calls during 1993. These calls usually involve questions about how to safely handle, cook, and store meat and poultry products. In addition to calls from the general public, Hotline managers fielded questions from over 750 media representatives, government and food industry professionals, educators, and other "information multipliers."

Public service announcements have been sent out to over 1,000 radio stations around the country. One of the families who lost a son in the Washington State outbreak, Vicki and Darin Detwiler, participated with us in this effort.

Enforcement

Secretary Espy has also directed FSIS to emphasize stricter enforcement of sanitation and other food safety requirements in meat and poultry plants. When necessary, tough corrective action is taken by USDA in problem plants.

In February of 1993, Secretary Espy directed FSIS to very strictly enforce procedures to ensure that all fecal, ingesta, and milk contamination is removed from beef carcasses. Although this stricter enforcement of the "zero tolerance" policy went into effect immediately, work on the uniformity of enforcement continued throughout last year. Guidelines on implementing the policy have now been provided to all beef plants, and the USDA employees at those plants. On January 10, FSIS instituted additional training of inspectors to ensure uniform enforcement of the zero tolerance policy at all beef plants across the country.

In the late Spring of 1993, Secretary Espy directed FSIS to conduct unannounced reviews of beef plants to assess the implementation of the "zero fecal" program. Of

⁵ Retained in Committee files.

the 90 plants reviewed, about a third were found to have serious enough problems to require immediate action, such as shutting down production lines. We have since revisited several of these plants and have found considerable improvement.

The Secretary also directed FSIS to establish a review and assessment office, which recently completed a special review of 26 turkey plants operating under the New Turkey Inspection System (NTIS). The results of the review were released last Friday. The review found that the NTIS program was working very well, but improvements could be made. This was the first review that included in-depth interviews with in-plant inspectors. Based on the results of this review, Secretary Espy has directed FSIS to improve NTIS by: retraining inspectors in NTIS; developing procedures for terminating the NTIS program in plants that are incapable of meeting inspection standards, thus returning them to the traditional inspection system; and reevaluating NTIS product standards, among other things.

Recently, the Review and Assessment office also began a series of 1,000 unannounced plant reviews throughout the United States. These reviews are targeting plants suspected of having compliance problems. As with all reviews we conduct, we are taking immediate action when problems are found—including stopping operations. Over 200 plants have already been reviewed and we plan to pick up the pace this Spring. We are sending a clear message that plants need to be on the alert and in full compliance with food safety requirements at all times.

Currently, 275 Federal plants, identified through special reviews and in the course of daily inspection operations to have significant problems, are operating under Progressive Enforcement Action (PEA), which is an intensified inspection program that can lead to withdrawal of inspection and closure of a plant if problems are not corrected. As only 90 plants were under PEA at the same time Secretary Espy took office, this represents a three-fold increase in Progressive Enforcement Action over the past year.

Through Secretary Espy's efforts over the last year and as part of the President's fiscal year 1994 food safety investment initiative, 200 additional inspector positions have been added at FSIS. Although these inspectors cannot see microbiological contaminants, there will be additional eyes, ears, and hands to observe and monitor carcasses and sanitary conditions in Federally inspected establishments. Secretary Espy has also made it a priority for FSIS to maintain existing staffing levels in plants. All too often in the past, inspector positions were left vacant when an inspector retired or resigned. We are filling these positions quickly.

Preharvest Activities

Our focus is not only on the slaughter and processing plants; it also includes the entire food chain from farm to table. For this reason, the Pathogen Reduction Program includes a preharvest food safety focus. Preharvest food safety deals with the beginning of the food chain—on the farm where meat and poultry production begins—and continues through transportation to the slaughterhouse. Preharvest food safety activities are primarily the responsibility of the Department's Animal and Plant Health Inspection Service (APHIS).

APHIS is uniquely qualified for preharvest food safety work because of its work in animal health, its traceback capability, and a longstanding relationship with State animal health and public health officials. We already have in each State an infrastructure ideally suited to conducting emergency traceback investigations and we periodically conduct mock animal disease emergencies to keep our field work force and investigation techniques well honed in the event of a real emergency. APHIS also runs the National Veterinary Services Laboratories, which are staffed and equipped to diagnose virtually any livestock or poultry disease and serve as reference labs for other diagnostic facilities across the country.

In addition, APHIS maintains a staff of animal health experts, statisticians and epidemiologists whose primary function is to monitor animal disease outbreaks, develop animal disease control models, and perform traceback investigations when called upon to do so. For example, months before the *E. coli* 0157:H7 in dairy heifers, which is the basis for national prevalence estimates of *E. coli* 0157:H7, as well as *Salmonella* and *Cryptosporidia*. From this study, we learned that there is no geographic pattern for *E. coli* 0157:H7, and that it appeared in less than 1 percent of those animals tested.

One of our future goals, and the core of APHIS' involvement in preharvest food safety, is the development of pathogen reduction models for use on the farm. APHIS' work on another foodborne illness, *Salmonella* enteritidis (SE), serves as a potential model for other preharvest programs. Under the SE traceback program, poultry flocks implicated in human outbreaks of SE are placed under restriction until the status of the flock is determined. While under restriction, eggs can only go to plants

for processing; they cannot be marketed as table eggs. If the flock is determined to be infected, restrictions remain in place until the flock tests negative.

Models for other health issues that affect meat and poultry will take some time to be developed, but are critical to minimizing the existence of foodborne pathogens on the farm, and preventing their spread to other points along the food chain. An integral part of developing these pathogen reduction models will be identifying critical control points and developing intervention strategies to address the problems most likely to occur.

APHIS' preharvest food safety operational goals for the current fiscal year include working with the U.S. meat and poultry industries to improve existing identification and traceback systems and promoting quality assurance programs. In addition, APHIS will hold a national meeting next month with industry and government leaders, universities, and consumer groups to facilitate preharvest food safety information exchange.

Microbiological Testing

As of October 1993, FSIS completed its first year of data collection for the microbiological baseline survey of steers and heifers and a final report has been completed. In this survey, 99 percent of all fed cattle slaughtered in the United States were included in the sample population. Over 2,000 cattle were sampled, and nine individual microbiological tests were conducted on each sample—including a test to detect *E. coli* 0157:H7. No pathogens of any kind were found on 85 percent of the carcasses. *E. coli* 0157:H7 was found on four of 2,081 carcasses tested, or 0.2 percent.

A similar survey is underway for bulls and cows. Surveys of poultry and swine have also been ordered by the Secretary. These surveys will help us understand what kinds and what levels of microbiological contaminants are present on the various species of animals after they have been slaughtered and inspected.

Also in October, USDA published the performance characteristics that FSIS expected new microbiological rapid tests to meet to be useful in a plant environment. In addition, we published a notice in the *Commerce Business Daily* requesting information on new technologies that may be applicable to rapid detection of low numbers of microorganisms on meat and poultry. Eight responses have been received, including a proposed technique that would permit us to detect the presence of bacteria through bioluminescence.

Rapid detection of microbial contamination on carcasses is a major concern of USDA. Scientists at the Agricultural Research Services' (ARS) Meat Animal Research Center in Clay Center, Nebraska have determined that a commercial bacterial test can be adapted to confirm high levels of microbial contamination on meat carcasses. The test currently takes about 50 minutes. ARS scientists are optimistic that this rapid test will allow FSIS and the meat and poultry industry to determine if a carcass has been grossly contaminated. This test is now being evaluated by FSIS and ARS.

FSIS is also embarking on a major initiative to integrate microbiological testing into its inspection activities. There are three components to this testing program:

Pre-Production Microbiological Sampling. FSIS will incorporate microbiological testing into the preoperational program already in use. Daily visual inspections to monitor sanitation programs in meat and poultry plants will be enhanced by random micro-monitoring. This sampling program will provide valuable information about the relationship between the visual appearance of facilities and equipment surfaces and the level of microbiological contamination. It will also provide inspectors with valuable experience in microbiological principles and sampling techniques that will be helpful as we incorporate more microbiological testing into the inspection program. A broad-scale pilot test of the program will begin in the Spring. National implementation in meat and poultry slaughter, and processing plants will be phased in beginning in October.

Slaughter Production Microbiological Sampling. FSIS will begin microbiological testing to monitor procedures carried out by a plant to remove visible fecal, ingesta, or milk contamination from livestock and poultry carcasses. A pretrial of this sampling program is now being conducted in five beef plants. A broad-scale pilot is scheduled to be carried out this Spring, and nationwide implementation in beef slaughter plants will begin in October 1994.

Processed Products Microbiological Sampling. FSIS is extending its current microbiological testing program for processed, ready-to-eat products to additional types of products not currently covered. Especially important is the fact that FSIS initiated microbiological testing of cooked, ready-to-eat meat patties produced in Federal establishments. This supports the regulation I mentioned earlier which mandated

cooking temperatures for precooked patties. Microbiological sampling for uncooked cured meat products began in October 1993 and for cooked patties in December 1993. Sampling will begin this month for dried, cured, or fermented products.

Public Health Focus

To improve coordination with public health officials, Secretary Espy directed FSIS to create a new liaison position with CDC. The liaison officer has been selected and began work very recently. This new position will help ensure that USDA has the most up-to-date information from CDC epidemiologists and medical professionals, thereby enhancing the public health activities of FSIS. The liaison officer will also help ensure that USDA is more involved in the tracking of outbreaks involving *E. coli* O157:H7.

In addition to the CDC liaison FSIS has hired, about 3 years ago, APHIS hired a full-time veterinary epidemiologist to facilitate communication and coordination between APHIS and CDC. This epidemiologist, working closely with his CDC counterpart, traveled throughout the Pacific Northwest investigating where the *E. coli*-tainted ground beef came from in the January 1993 outbreak. Together, they developed recommendations for further research that could help reduce the spread of foodborne pathogens at almost every stage of the food chain from farm to restaurant.

Secretary Espy has also made progress on his plans to create a public health division within FSIS. I recently interviewed two physicians for the position of public health advisor, who will head that division, and we hope to have someone selected very shortly.

Public Participation

In January of this year, USDA published in the FEDERAL REGISTER, a notice announcing plans for a roundtable on the Hazard Analysis and Critical Control Point (HACCP) system. HACCP is an internationally recognized process control system to prevent problems from occurring during the course of production as opposed to after the product is produced. The roundtable is intended to be a discussion of HACCP and how it can best be carried out in meat and poultry establishments.

Conducting the roundtable also meets other goals of Secretary Espy's—to ensure that all voices are heard (including consumers), industry, farmers, medical professionals, researchers and regulators, to ensure that all opinions are considered; and to ensure greater public participation in the decisionmaking process. We encourage all Members of Congress to participate in this important process; your views and insights would be most helpful.

Regulatory Initiatives

In September 1993, a new regulation went into effect that prescribes the procedures for cooking and handling cooked meat patties in Federal plants. I should note here that work began on this rule shortly after the *E. coli* O157:H7 outbreak in Minnesota in the late 1980's. Under this administration, we will not permit so much time to pass before issuing these types of much needed regulations.

The Department is in the process of developing a legislative proposal that would provide the Secretary the necessary statutory authority to ensure that there will be no gaps in our ability to address food safety issues from the farm to the table. We will submit this proposal to Congress after appropriate review by the Administration.

Interagency Coordination

In keeping with another promise Secretary Espy made to this subcommittee last year, I want to mention here the recent formation of the Pathogen Reduction Task Force. This task force is responsible for leadership, coordination and oversight in USDA's efforts to reduce pathogens in meat and poultry. The Secretary has designated me to lead the task force, and our first organizational meeting was held yesterday.

As this task force moves forward, we will be examining the results of the many projects USDA already has underway. The results of these projects may be the key to where we head in the future. We anticipate adding more initiatives as we move forward and as new technology becomes available. We believe it is critical to maintain a systems approach to integrate and focus the many resources in the Department, including research and education components in our efforts to reduce pathogens. The Task Force includes members of other Federal agencies, such as CDC and FDA, to ensure that all of our efforts are well-planned, coordinated, and implemented effectively.

Summary of Plans for 1995

In Fiscal Year 1994, Congress approved the Administration's request for an additional \$8 million for pathogen reduction activities. In Fiscal Year 1995, the Administration, as part of the President's Investment Initiatives, is requesting an additional \$25.8 million. The additional funds for pathogen reduction will be targeted at improving the system from the farm to the table. FSIS would receive \$14.0 million; APHIS, \$5.7 million; the Economic Research Service, \$0.7 million; and \$14 million for research and extension.

With funds requested in the Fiscal Year 1995 budget, we will expand our multi-agency efforts for pathogen reduction. At the preharvest end of the system, a traceback system for determining the sources of microbiological contamination at the farm level will be implemented. Efforts will also be undertaken to develop educational programs for food producers and handlers to encourage adoption of production practices that limit contamination by pathogens and other hazards. For the slaughter and processing segment of the system, inspectors will be trained in the latest food safety techniques, rapid testing methods will be developed, and new production practices that may reduce or eliminate contamination will be evaluated. We also propose to hire an additional 200 inspectors to ensure that we have all the necessary personnel in place to ensure compliance with food safety standards.

These efforts will be supported by the Department's research agencies. Consistent with the farm to table approach to reducing pathogens, USDA researchers will devote resources to develop improved production methods and will strive for advances in processing technology, including new meat and poultry inspection tests to rapidly identify bacteria levels and improved slaughter methods. Newly developed technologies will be demonstrated to producers and handlers of meat and poultry products through increased food safety education.

In summary, Mr. Chairman, Secretary Espy has pledged that we will have a science-based inspection system, more focus on public health, tougher enforcement, improved consumer education—especially safe handling labels. That's the direction we're going now and the direction we will head in the future.

I want to take this opportunity to compliment the Members of this subcommittee for your dedication to the issue of food safety, and to assure you that we in USDA stand ready to work with you—forming a partnership with Congress, Federal, State and local governments, industry, parents, health officials, scientists, consumers, producers and others—to seek answers to these pressing questions of food safety.

Thank you again, Mr. Chairman, for inviting me here today. I'm happy to answer any questions you or other Members of the subcommittee have.

CAROL TUCKER FOREMAN*

Mr. Chairman, I am Carol Tucker Foreman. I appear today on behalf of the following members of the Safe Food Coalition: American Public Health Association, Center for Science in the Public Interest, Consumer Federation of America, Consumers Union⁷, Food and Allied Service Trades (AFL-CIO), Government Accountability Project, National Consumers League, Public Citizen, Public Voice for Food and Health Policy, Safe Tables—Our Priority, and United Food and Commercial Workers International Union (AFL-CIO).

This hearing is a followup to one you held February 5, 1993 shortly after the tragic West Coast outbreak of *E. coli* 0157:H7, traced to insufficiently cooked, contaminated ground beef. That outbreak caused over 500 illnesses, claimed the lives of four children and cost millions of dollars in medical care. The *E. coli* outbreak was, however, only the most recent manifestation of a serious public health issue.

According to the Centers for Disease Control and Prevention (CDC) and the Carter Center, there are between 6.5 and 80 million cases of and 9,000 deaths from bacterial foodborne illness each year in the United States. USDA's Economic Research Service has estimated that foodborne illness costs this Nation about \$2 to \$4 billion each year in medical costs and lost productivity. These are conservative estimates because the foodborne disease reporting system is acknowledged to underestimate the number of illnesses and deaths.

*Carol Tucker Foreman is president of the Washington, DC, public policy consulting firm, Foreman & Heidepriem, Inc. From 1977-81, she served as Assistant Secretary of Agriculture for Food and Consumer Services. Her responsibilities included direction of the Nation's meat and poultry inspection programs.

⁷The Safe Food Coalition, an alliance of consumer advocacy, senior citizen, whistleblower protection and labor organizations was formed in 1987 to work for improvements in the Nation's food inspection programs. Consumers Union is not a formal member of the Coalition, but endorses this testimony.

The most common sources of bacterial foodborne illness are meat, poultry, eggs and shellfish, and it is clear that major changes need to be made, from production to consumption, in the way food is grown and processed, and how it is handled by retailers, food service personnel and consumers.

At the 1993 hearing, the newly appointed Secretary of Agriculture, Mike Espy, and his staff outlined steps the Department would take to improve the meat and poultry inspection program and reduce the possibility of another *E. coli* outbreak. You have asked the Safe Food Coalition to appear here today to discuss USDA's progress in meeting those goals.

USDA HAS MADE SOME PROGRESS IN RESOLVING THE PROBLEMS THAT PLAGUE THE MEAT AND POULTRY INSPECTION SYSTEM

A year ago, we were very critical of USDA. As recently as November 1993, we pointed out that the Department had failed to put into effect the pledges the Secretary made. Today, we are somewhat more optimistic. Although progress has been painfully slow, it is clear that the Administration is trying to address the problems, that the Secretary understands the barriers to progress and he is making some progress in overcoming them.

Let me review the pledges and the progress:

MOVING MEAT AND POULTRY INSPECTION TO A PUBLIC HEALTH AGENCY

In the National Performance Review, the Clinton administration recognized that meat and poultry inspection is, first and foremost, a public health program and will be most effective if it is transferred out of USDA and into a public health agency. We have long advocated such a position.

HIRING ADDITIONAL INSPECTORS

The administration hired 200 additional inspectors in order to shore up an understaffed force while it attempts to develop new methods of inspection.

INCREASING UNANNOUNCED INSPECTION REVIEWS

The Secretary has increased the number of "unannounced" inspection reviews to improve the operation of the existing system. These reviews are an important mechanism for ensuring the integrity of the system. We think they will be even more effective if the Department makes it a practice to release the results of the reviews to the public.

REQUIRING THAT MEAT AND POULTRY CARCASSES BE FREE OF FECAL CONTAMINATION

Eleven months ago, the Secretary pledged to institute a zero tolerance for fecal contamination of meat and poultry because feces, milk and ingesta may harbor dangerous bacteria that cause foodborne illnesses such as *Hemolytic Uremic Syndrome*, *salmonellosis* and *campylobacteriosis*. The job is half done. The Department has instituted and issued guidelines for enforcing a policy that inspectors must not approve beef carcasses contaminated with feces.

However, last May, Secretary Espy said he intended to extend the "zero tolerance for fecal contamination" policy to poultry. That pledge has not been fulfilled. Poultry carcasses are frequently soiled by feces and ingesta. Some USDA studies indicate that up to 60 percent of broiler carcasses are contaminated with pathogenic bacteria. Current USDA policy allows raw poultry that has been contaminated with feces to be stamped "inspected for wholesomeness—USDA" and sold to the public.

PLACING SAFE HANDLING INSTRUCTIONS ON MEAT AND POULTRY PRODUCTS

Secretary Espy is close to achieving this goal and we think it is the most important accomplishment of his tenure.

To the casual observer, truthful, accurate, clearly stated and simple handling instructions would not seem to be a major burden on the Government or the industry. Consumer groups have been seeking this goal for 20 years and it is not yet a reality. USDA's failure to respond is just one example of how difficult it is for the Department to make changes that serve consumers and protect public health.

Twenty years ago, consumer and public health activists went to court seeking to force USDA to require safe handling labels on meat and poultry products. In 1975,

the U.S. Court of Appeals ruled that the provisions of the meat and poultry inspection acts "give the Secretary discretion to determine what labeling, if any, will be required in addition to the official inspection stamp." *APHA v. Butz*, 511 F.2d 335 (D.C. Cir. 1974).

For 20 years, nothing happened.

Last February, after the *E. coli* outbreak, Secretary Espy told this committee,

" . . . So we need to move right away to developing instructions to promote safe handling and cooking of raw meat and poultry, particularly hamburger."

Despite this pledge, the Food Safety and Inspection Service (FSIS) took no action until sued once again, this time by the Beyond Beef Campaign. In August 1993, the Department published an interim final rule requiring that labels be applied by October 15. Consumer and public health groups reacted favorably. However, the Department was not able to persuade the Federal courts that it was justified in bypassing the usual notice and comment rulemaking and there is, as of today, no requirement for safe handling labels in effect.

Finally, last December USDA dropped its appeal and published a proposed rule and provide a comment period. We eagerly await the final regulations, but the first anniversary of the *E. coli* outbreak passed with no final action having been taken.

It is truly unfortunate that USDA has been unable to implement the Secretary's pledge in a timely manner. When you consider the number of people who have suffered or died from foodborne illness over the past 20 years, the Department's failure to use its acknowledged power is unconscionable.

INSTITUTING A SYSTEM TO TRACE MEAT AND POULTRY BACK TO ITS ORIGIN

The best place to stop contamination is at the source. However, USDA has no program to trace meat found to be contaminated with harmful bacteria or chemical residues from the slaughterhouse back to its point of origin. Nor has the Department acted effectively on this issue.

On February 5, 1993, Secretary Espy said:

"We can do more right away to improve the requirement that these Federally inspected slaughterhouses keep better records. I would like to see that (traceback) become a standard throughout the slaughter industry."

Nothing more happened. No rule was proposed. On September 17—7 months later—Administrator Russell Cross told the Physicians Committee for Responsible Medicine,

"It is not correct that we have dropped plans for a traceback system . . . USDA does not now have authority under the meat and poultry inspection acts to require mandatory animal traceback. Neither does it have authority to prevent the movement of animals to slaughter, except for certain infectious animal diseases . . . However, FSIS has prepared a series of legislative proposals . . . to give the Secretary authority to control human pathogens in food producing animals . . ." (Letter to Dr. Neal Barnard, September 17, 1993)

No proposal was sent to Congress before it adjourned last November.

Traceback is not a new idea. It was endorsed by the National Academy of Sciences (NAS) in 1985. Even that recommendation wasn't new. Consumer groups and some processors have advocated it for years. In 1980, the Department of Agriculture drafted, OMB cleared and the Carter administration submitted to Congress a request for authority to trace meat and poultry back to their source. It is hard to understand, given this history, why the proposal is still "in clearance" at USDA.

DEVELOPING RAPID ON-LINE TESTS FOR BACTERIAL CONTAMINATION

Secretary Espy said this was one of his goals and recently he said that a test for *E. coli* may be near development. We eagerly await both the development and implementation of tests for this and other bacteria.

The record is not very impressive. In 1985 the National Academy of Sciences recommended that USDA develop rapid on-line tests to detect bacterial contamination of raw meat and poultry before the product leaves the plant. The Department has not made significant progress toward this goal.

The 1985 NAS Report, *Meat and Poultry Inspection: The Scientific Basis of the Nation's Program* stated:

"FSIS (should) intensify its current efforts to control and eliminate contamination with microorganisms that cause disease in humans. Such efforts

should include evaluation of rapid diagnostic procedures for detecting microorganisms, especially species of *salmonella* and *campylobacter*." (National Academy of Sciences, *Meat and Poultry Inspection: the Scientific Basis of the Nation's Program* (hereafter referred to as NAS), 1985, p. 4)

"As of 1984, only a few quick tests have been developed, although it is widely recognized that online serological testing of animals could dramatically reduce the need for subjective decision making that has marked meat and poultry inspection for nearly a century. The committee maintains that much more could have been done by now." (NAS, p. 161)

Almost exactly 4 years later, on April 11, 1989, FSIS Administrator Lester Crawford, testified before this subcommittee, and acknowledged that the Agency had not yet begun developing rapid tests for bacterial contamination. He stated, "analytical testing . . . including both laboratory and rapid in-plant tests to detect contamination . . ." were part of "the next phase" of the Agency's program. (U.S. House of Representatives Committee on Government Operations, April 11, 1989, p. 180)

Dr. Crawford stated further,

"We are developing a proposal announcing criteria for streamlined approval of new diagnostic and screening tests" . . . for microbial and chemical contamination. (Committee on Government Operations, p. 171)

In February 1993, the present FSIS Administrator Russell Cross replayed the theme,

"Regrettably, there is no in-plant test developed and approved for microbiological testing of raw meat and poultry products. This is one of our highest research priorities and we expect significant progress in this area in the future." (*Testimony before Washington State Senate, February 2, 1993*)

On October 21, 1993, FSIS published in the FEDERAL REGISTER a notice to inform interested parties of the criteria that FSIS will use to evaluate and/or develop new test results. The notice included such criteria as the need for "faster results" than the present 24-hour tests.

Recently, Secretary Espy has spoken optimistically of the possibility of a rapid test for *E. coli* 0157:H7. However, FSIS still has no organized program to develop rapid tests to detect a range of pathogenic organisms that contaminate raw meat and poultry. The Agency has established no goals or timetables for completing development and actually putting the tests to work in plants.

These tests should be an integral part of the Hazard Analysis and Critical Control Point (HACCP) program for meat and poultry inspection. The National Advisory Committee on Microbiological Criteria for Food (NACMCF) states that microbial testing in HACCP is of limited value in monitoring critical control points *because it takes too long*. (NACMCF, "Hazard Analysis and Critical Control Point System," March 20, 1992, p. 2) (Emphasis added.) If rapid tests were available, they could add to the effectiveness of a HACCP program.

DESIGNING A MEAT AND POULTRY INSPECTION SYSTEM THAT WILL ENCOURAGE PRODUCTION OF MEAT AND POULTRY PRODUCTS THAT ARE CLEANER, SAFER AND LESS LIKELY TO CAUSE FOODBORNE ILLNESS

Secretary Espy has pledged a new kind of inspection system. There is virtually universal agreement that this is necessary. The Safe Food Coalition, along with the NAS, the industry and the Federal Government, believes that an HACCP system holds promise for improving food safety and public health protection.

However, we believe it is important to understand the nature of HACCP, the extent of its application to food safety, how USDA intends to apply it to meat and poultry, and whether USDA's HACCP system will include elements which we believe are essential to its effective use as part of a government inspection system before we can endorse it as a step toward improving public health. Like all other science, the HACCP program should be able to offer, in advance of its implementation, empirical evidence that it will lead to meat and poultry that are cleaner, safer and less likely to cause foodborne illness.

We have not seen that evidence.

Developing Infectious Dose Data. To develop an effective new system, USDA must acquire the information the NAS said is basic to a science-based public health program. The Department does not know how much of a particular pathogen it takes to make someone sick. This infectious dose information is the first vital step in building an inspection system geared to public health protection. If USDA tries to build a new inspection system without these data, it may create a new program that

does not keep bacteria below a critical level. The Department may end up spending enormous amounts of time and money to build a new program that is less effective than the present one.

Setting Guidelines for Acceptable Levels of Bacterial Contamination. USDA must establish guidelines for maximum acceptable levels of bacterial contamination in raw meat and poultry stringent enough to reduce the likelihood of foodborne illness. Today, FSIS has no guidelines at all. There is no USDA provision that says that a piece of meat grossly contaminated with *E. coli* 0157:H7 cannot be sold to the public. There is no intention for USDA to include such guidelines in its HACCP program.

FDA has guidelines for maximum acceptable levels of *E. coli* in raw crabmeat and of *salmonella* in raw shrimp, but USDA maintains it is impossible to provide the same sort of guideline for raw meat and poultry.

Determining the Impact of Processing and Distributing Meat and Poultry by Determining the Microbiological Profile of Raw Meat and Poultry at Every Step from Slaughter to the Retail Case. USDA is investing substantial resources in baseline studies of beef and poultry, despite the fact that scientists from other government agencies have been critical of the structure of the beef study. The critics have argued that the study takes samples at a place where contamination is least likely to occur, and that the analytical methods being used are too insensitive to detect harmful levels of microbial contamination.

The Safe Food Coalition believes that it would be even more useful to institute a vertical sampling to determine levels of bacterial contamination at every step from slaughter to processing. This could help us understand where contamination occurs, what processing and distribution factors encourage bacterial growth and what steps might be taken to reduce bacteria levels as much as possible and as quickly as possible.

DEVELOPING AN INSPECTION PROGRAM THAT UTILIZES THE HAZARD ANALYSIS AND CRITICAL CONTROL POINT SYSTEM

HACCP is not a health and safety regulatory program. It is a process control that a company can apply to virtually any type of manufacturing. It identifies points at which problems may arise and prevents the problem by controlling what happens at the points. Some food companies now employ HACCP systems, primarily to improve the shelf life of their products.

The only government regulatory applications of HACCP to food manufacturing now in place are FDA's programs for low-acid canned foods and infant formula. These programs have been effective, but these products are cooked and, therefore, present different problems than raw meat and poultry. Recently, FDA proposed extending the regulatory use of HACCP to seafood. We believe that the FDA's HACCP proposal is a good first step. It has an impressive data base. FDA has done some of the hard basic science USDA must undertake before it attempts to launch an HACCP program for meat and poultry.

However, FDA's HACCP proposal lacks important regulatory authority, which is essential to a program that holds out the imprimatur of Federal inspection to the American people.

The Safe Food Coalition believes the following elements are essential to a Federally mandated HACCP program for meat and poultry:

- Demonstrate that the application of the USDA HACCP program will result in cleaner, safer food that is less likely to cause foodborne illness.

- Develop guidelines for acceptable levels of bacterial contamination.

- Develop data to demonstrate that the visual and physical tests applied in monitoring and verification are accurate and adequate to improve food safety. FSIS has indicated that the HACCP system will use a number of the same visual and physical checks that are part of organoleptic inspection to monitor and verify critical control points. The Agency should be able to demonstrate how these checks, applied in the HACCP system, will result in a safer product.

- Make available to the public all plant HACCP plans and records relating to actions taken by Federal inspectors to enforce safety in HACCP plants. USDA's HACCP may constitute a massive "privatization" of a previously public function. Under the present inspection system, Federal inspectors review plant operations each day and then sign an inspection report. The report notes any problems which had to be remedied to produce a safe product and is available to the public. The NACMCF recommended that HACCP plans "must be considered proprietary information that must not be made available outside the regulatory agency." (Generic

HACCP for Raw Beef, p. 36) FSIS should not follow this recommendation. The plans must be publicly available.

—Undertake a full public examination of all issues related to HACCP before publishing regulations. The Safe Food Coalition is pleased to note that USDA seems to have recognized the value of this step. A Roundtable discussion has been scheduled that will include all of the interested constituencies, albeit in ratios that do not reflect that USDA views this as a public health issue. Industry representatives have five seats at the table; public health experts have two. We do not think that a panel put together by the Food and Drug Administration, for example, would assign public health experts so little representation in constructing a program designed to protect public health.

However, since consumers were prohibited from participating in key HACCP decisionmaking meetings earlier, we welcome this development and we look forward to participating in the program.

PROVIDING AN ADEQUATE LEGAL AND REGULATORY FRAMEWORK FOR A NEW INSPECTION SYSTEM

FSIS officials have stated that HACCP will not take the place of the existing inspection program. However, the former administrator Russell Cross stated that implementation of HACCP would have a "drastic effect on the way inspectors do their jobs." (Press Conference, May 27, 1993). The National Advisory Committee on Microbiological Criteria for Food, which has advised FSIS extensively in its development of HACCP has indicated that HACCP would replace specific tasks now carried out by Federal inspectors pledged to protect public health.

It seems certain that the implementation of HACCP will lead USDA to propose ending the traditional "continuous inspection" that has characterized meat and poultry inspection. The present system has an insufficient scientific base, but the presence of inspectors in the plant provides some assurance that basic sanitation standards are usually met. These standards reduce the possibility of extreme bacterial contamination and foodborne illness. The Safe Food Coalition believes any HACCP program must include the following elements:

—Unannounced, random inspections by Federally sworn personnel, with frequency based on the risk associated with the operation being performed, the product being produced and the compliance history of the plant.

—Independent certification of hazard analysis experts and of plant personnel conducting HACCP procedures.

—Public access to all plant records related to critical control points, verifications, deviations and corrections.

—Monthly publication of names of plants that violate HACCP requirements.

—Authority to impose civil penalties on companies that violate inspection regulations or laws.

—Whistleblower protection for plant employees. If plant employees replace Federal inspectors in providing public health protection, the law must protect them against losing their jobs if they report public health hazards.

Finally, Mr. Chairman, there are additional steps that USDA can take now to improve the existing system of inspection. The Clinton administration can and should bring new leadership to FSIS. This public health program needs a leader who brings an exceptionally strong record in development and administration of a public health regulatory program and a reputation for commitment to science and health.

Secretary Espy has said he wants meat and poultry inspection to be a public health program. Recently, the Department established a "public health advisor" position in FSIS. It is located three levels down in the Food Safety and Inspection Service, a long way from the Secretary of Agriculture. The very title of the position indicates that the position has no line authority. If the Food Safety and Inspection Service is truly a public health agency and if the goal of meat and poultry inspection is to protect public health, public health experts should lead the Agency, not be powerless advisors stuck in the bowels of the bureaucracy.

Americans expect their food to be safe. Both the U.S. Government and industry officials frequently claim that U.S. consumers enjoy the safest food supply in the world. The Department of Agriculture reinforces this claim by stamping every package of meat and poultry with a seal stating it has been "inspected for wholesomeness and passed by the U.S. Department of Agriculture." The evidence is overwhelming that that seal is not truthful. We must change that.

J. PATRICK BOYLE

My name is J. Patrick Boyle, and I am president and C.E.O. of the American Meat Institute (AMI), the national trade association representing packers and processors of meat, turkey and other animal protein products. Our member companies slaughter and process more than 90 percent of the meat and over 60 percent of the turkey produced in the United States.

Since AMI testified before this subcommittee a year ago, there has been an avalanche of activity to find ways to prevent further *E. coli* outbreaks and make the food supply safer.

Actions speak louder than words, and I want this subcommittee to know that the meat industry is taking action—to prevent foodborne illness, to promote food safety research and education and to reform meat inspection. In the past year alone, we have made real progress:

- The AMI Foundation has raised nearly \$4 million to find new ways to prevent or destroy harmful bacteria in raw meats before the foods leave our plants.

- We have confirmed that low-level irradiation and acidic carcass mists dramatically reduce bacteria on meat.

- We are now researching the anti-microbial effects of carcass rinses, electronic pasteurization, pulse-light technology and alkaline carcass mists.

- Our foundation has joined the Lois Joy Galler Foundation to find a cure for *Hemolytic Uremic Syndrome*, a devastating disease that can result from *E. coli* 0157:H7.

- If we could detect and treat this disease better, then we may be able to prevent the severe and sometimes life threatening complications in children.

- We are aggressively training food safety specialists from meat and poultry plants to use a state-of-the-art food processing system called Hazard Analysis Critical Control Points, or HACCP.

- This system has been endorsed by the National Academy of Sciences, the Food and Drug Administration and many other scientific, government and industry groups.

- HACCP forms the basis of a proposed new Federal seafood safety program.

- AMI supported mandatory safe handling labels on raw foods, and many companies are already voluntarily labeling raw meats with safe handling information.

- AMI developed and helped distribute millions of these safe food handling brochures to consumers, restaurants, public health officials and educators.

- To devise a 21st century blueprint for farm to table safe food production, AMI has joined a "Blue Ribbon Panel" of meat industry, cattle ranching and fast food industry leaders.

- This group will release its recommendations in the near future.

Senator Daschle, after more than a year of talking and researching and meeting and arguing, it seems to me that all of us with a stake in this issue—consumers, industry, government and others—need less talk and more concrete action. Someone needs to step forward and lead the way for all of us to a safer meat and poultry supply.

The meat industry, through the American Meat Institute, is in the best position to do that. We have the will to do it, we have the means to do it and, quite frankly, we have the moral obligation to do it.

I would like to share with you AMI's vision of the safer meat and poultry production system of the future.

Safer Meat and Poultry for the Future

This safer system must have one primary goal: to prevent human health hazards from farm to table. It is a goal supported not only by AMI, but by two separate 1985 reports from the National Academy of Sciences (HAS) and by Vice President Gore's 1993 report on *Reinventing Government*.

How do we prevent hazards? We agree with HAS that "the most effective way . . . is to control (hazards) at their point of entry into the food chain." In other words, we start on the farm.

The livestock and poultry farms of the future will use HACCP principles to design, monitor and adjust their animal husbandry practices. They will keep records

on both the source and destination of their animals to facilitate tracebacks. They will conduct research to identify types of animals or farming practices that increase or decrease human health risks. They will use immunological testing to screen animals for pathogens or disease. When those animals arrive at packing plants, we will already know which ones might need special treatment or closer scrutiny to prevent foodborne hazards.

The packing plants of the future will design, monitor and control their own set of hurdles to human health hazards in meat and poultry. First, they will be required by government to operate using HACCP principles. To accomplish this, AMI formally petitioned the Department of Agriculture this morning to initiate a mandatory HACCP rule similar to the new seafood safety rule proposed by the Food and Drug Administration.

Mandatory HACCP for the meat and poultry industry would follow guidelines set by the National Advisory Committee on Microbiological Criteria for Foods. The committee has consistently said that "controlling, monitoring and verifying processing systems are more effective than relying upon end-product testing to assure a safe product." HACCP forces companies to control their processes.

Packing and processing plants would be required to employ a certified, HACCP technician in every plant. There would be an approved HACCP training and certification program to assure consistent training standards. There would be independent audits of plants' HACCP programs to make sure they are adequately preventing public health hazards.

Under the AMI plan, packing plants would be required to keep detailed records not just on the critical control points they monitor under HACCP, but also on the origin and destination of their products. More detailed livestock records would facilitate animal traceback, and better product distribution records would facilitate product tracing or recalls.

In fact, all meat and poultry processors would be required to have a product recall plan to make it easier to control exposure to products which might, despite all the hurdles, carry a human health hazard.

And finally, plants would be required to use certain technologies known to prevent, reduce or destroy human health hazards. Industry and government would work together to identify and encourage development of those technologies.

Once meat and poultry leaves Federally inspected plants, there is still a need for vigilant control. So we advocate a safer system in which all foodservice and retail establishments would use HACCP to control the way they handle, process and prepare meat, and poultry, in order to prevent public health problems.

Retailers and foodservice operators would improve their recordkeeping to make it easier to trace or recover product that might pose a health hazard. They would improve their employee food safety training to prevent mishandling, cross contamination or undercooking. The Federal Government would improve its oversight of retail and foodservice establishments and work more closely with local authorities.

A safer meat and poultry system would also involve consumer initiatives. This education would help to prevent practices, which could lead to foodborne illness in the home. AMI advocates safe handling labels for consumers on packages of raw meat and poultry, and consumer education about food safety through the food and retail industries, the Government, the public health community and the media. Educational outreach efforts would focus on consumers most "at risk" of developing a foodborne illness—such as children, the elderly and the immunocompromised.

This is what the meat and poultry industry is prepared to do to make its products safer. Government needs to make changes to encourage these safe food production practices.

Modernized Meat and Poultry Inspection

We believe the Government's modernized meat and poultry inspection program must follow HAS recommendations and be driven by science, not politics; grounded in human health protection, not animal disease detection, and modeled after the most successful and efficient food safety control system, HACCP.

Consumers cannot expect safer foods if government does not share the vision of safer food through safer food production processes. It may come as a shock to some that the safety of our Nation's food supply does not depend on government inspection programs—no matter how modern or efficient. Safer food comes from safer food production processes, which are created, conducted and controlled by industry—farmers and ranchers, food processors, supermarkets and restaurants.

Government must encourage those practices by embracing the HACCP approach for its own programs. To those who question this approach, let me read from the 1985 HAS report on microbiological criteria for foods: "Microbiological standards for raw meats will prevent neither spoilage nor foodborne illness and thus do not

appear warranted. Instead, application of the HACCP system to the entire processing and distribution chain . . . should be used to produce a product with satisfactory . . . public health safety."

We need a new meat and poultry inspection system that uses quantitative risk analysis to pinpoint and prioritize food safety risks in the production of meat and poultry and allocates oversight resources accordingly. It should expand food safety research to identify new technologies and monitoring methods that make the food supply safer.

Government has begun to move towards such a HACCP-based inspection system, particularly in processing plants in which previously-inspected meat is further processed. In fact, the HACCP approach to food regulation has already proved successful. HACCP-based requirements for producing cooked roast beef in the 1970's led to a dramatic drop in salmonellosis. The FDA's low-acid canned food regulations and USDA's successful residue monitoring program are both HACCP based rules designed to control safe processes—and they work.

We believe inspection in meat and poultry processing plants should complete the evolution to a HACCP approach immediately. In slaughtering plants, we would envision a longer-term evolution to HACCP-based inspection—but we are adamantly opposed to a meat and poultry inspection system that maintains the *status quo*, while the industry moves aggressively towards Government-mandated HACCP operations.

Conclusion

I have shared with you AMI's vision of a safer meat and poultry production system, as well as a dramatically different government oversight program. We are committed to taking the necessary action to revolutionize both.

The bottom line is that industry bears responsibility for and ultimately controls the safety of its products, and it is up to industry to solve this problem. From farmers to processors to retailers and restaurants—all of these businesses, all of these people, working together, can solve this problem. We look forward to working in concert with government and consumers to bring needed change throughout the food production system.

DR. J. GLENN MORRIS, JR.

It is a pleasure to have this opportunity to speak before you today. I am a physician/epidemiologist on the faculty of the University of Maryland School of Medicine, and a board-certified specialist in infectious diseases. In contrast to others who have given testimony, I do not represent a specific interest group. However, I have been involved with three National Academy of Sciences expert committees dealing with food safety: I was on the 1987 committee which reported on use of risk assessment in poultry inspection, I served as a consultant to the 1990 committee which evaluated the USDA Streamlined Inspection System for Cattle (SIS-C), and I was a member of the 1991 committee dealing with seafood safety. In the early 1980's, I served as an Epidemic Intelligence Service Officer at the Centers for Disease Control, with responsibility for foodborne disease surveillance. At the present time, I am a member of the National Advisory Committee on Microbial Criteria for Food. I would like to speak to you today as a physician, a specialist in infectious diseases, and a scientist.

I will not go into great detail regarding the most recent surveillance data from the Centers for Disease Control; it is my understanding that these data have been included in a separate document provided to the committee by CDC. I would note, however, that the data indicate that *E. coli* 0157:H7, or enterohemorrhagic *E. coli* continue to be an important cause of foodborne illness in this country, with more than 17 outbreaks reported within the past year. By way of comparison, only 25 outbreaks were reported in the preceding 11 years. The increase in outbreaks in 1993 can be attributed in large part to the publicity surrounding the Jack-In-The-Box cases, which alerted physicians to the diagnosis and prompted laboratories to undertake the specialized testing necessary to identify the organism. Nonetheless, these data indicate that 0157:H7 disease is a real and continuing problem, extending well beyond a single outbreak or a single fast food chain.

It is also likely that these 17 reported outbreaks are only the "tip of the iceberg." Many 0157:H7 infections are never diagnosed, either because the patient does not consult a physician, the physician fails to perform a stool culture, or, even if a culture is performed, the laboratory to which the culture is sent lacks the technical ability to identify the organism. Illness is characterized by bloody diarrhea. Depending on the population, hemolytic-uremic syndrome may occur in <4% to 22% of in-

fectured persons. Persons with hemolytic-uremic syndrome have bleeding, break-down of their red blood cells, and go into acute renal failure. Again depending on the population, mortality rates can range from <10 to >90%. *E. coli* 0157:H7 can be transmitted via a number of routes, including person-to-person transmission within homes and day care centers, by contaminated water, and by food. The most common route, however, appears to be through consumption of insufficiently cooked ground beef. It is this latter observation which has focused attention on the role of meat inspection—and FSIS—in disease prevention.

Unfortunately, as this committee is aware, our current meat inspection system is a relic of the early part of this century. It is based on organoleptic inspection—simply looking and feeling—and does not address issues relating to bacterial contamination of meat. Expert committees at the National Academy of Sciences and the GAO have looked at the current inspection system in depth in a series of studies. A common theme through these reports is the idea that the current system should be replaced with a scientific, risk-based inspection system that is targeted toward human disease and disease prevention. The 0157:H7 outbreaks highlight the need for this type of approach. While USDA has expressed a willingness to move toward implementation of such a system, it is not an easy process, and progress has often occurred at speeds that can be best described as glacial.

Just to briefly summarize, what exactly is necessary for implementation of a risk-based inspection system? At the most basic level, there are four elements which are critical to development of such a system.

1. There is, first and foremost, a need for data; development of rational risk management programs is dependent on having the data necessary for risk assessment. A common lament through all of the National Academy reports is the almost total lack of such data. Data needs include epidemiologic data on human illness to identify foodborne hazards and characterize risk, and microbiologic data to assess the probability of exposure to these hazards.

In looking specifically at the 0157:H7 problem, there are investigators developing some very interesting data on the ecology of the organism—where it lives, and the factors which determine how and why it colonizes certain animals and certain herds. However, there is still a great deal we need to know about *E. coli* 0157:H7 and its transmission among both humans and animals. While USDA has begun to support research in food safety, there has not been a major, systematic push to obtain data needed for accurate risk assessment. There has also been a failure to fully exploit outbreak data, to try to determine whether there are specific plant characteristics which may increase the risk of producing contaminated meat; this, in turn, reflects ongoing problems in developing traceback capabilities.

2. There is the need for a structure around which to build a risk-based inspection system. At this time HACCP is generally accepted as the best structure for such a program. It should be emphasized, however, that HACCP is simply a structure, not a cure-all, and is only as good as the data around which it is built. Commendably, USDA is moving toward implementation of HACCP systems. Unfortunately, the data on which these systems is based do not always appear to be of optimal quality.

3. There is a need for the appropriate scientific tools to obtain data on an ongoing basis. From a microbiologic standpoint, this translates into the need for rapid diagnostic techniques, to permit bacterial contamination to be identified “on-line” at critical control points. Methods which would permit identification of pathogenic organisms such as *E. coli* 0157:H7 in a matter of hours are now available. I have discussed the need to implement such technology with Dr. Cross; while he was agreeable, his comment was that it “couldn’t be done” because of regulations, the difficulties involved in introduction of new technology, and similar constraints.

4. There is a need for an innovative, multidisciplinary team to direct such changes. What the National Academy has proposed is a radical reshaping of inspection policy. National Academy and GAO reports have repeatedly taken USDA to task for failure to follow Academy recommendations, raising serious questions about whether the Agency has the initiative, or skills, to implement such a system. Events since the 0157:H7 outbreak of a year ago have not provided any reassurance that this has changed. The much vaunted Pathogen Reduction Plan discusses the problem, but is short on actual implementation, with few substantive or innovative programs to get the job done.

In their defense, I am well aware that USDA has been shackled by current regulations. There is clearly a need for new enabling legislation which will

permit food safety and food inspection to move into the 21st century. Unfortunately, again, USDA has not aggressively pursued such legislation.

To summarize, 0157:H7 disease is still with us, and there is no indication that it will disappear any time in the near future. A key element in control of this organism is implementation of a scientific, risk-based inspection system for meat and meat products. There have been numerous studies and voluminous documents dealing with this issue, almost all of which have come to the same conclusion. We don't need any more studies—we just need some action. If we are to address the 0157:H7 issue in a meaningful way, there must be a major restructuring of food inspection systems. This needs to be done by an innovative, multidisciplinary team, backed by appropriate enabling legislation. I would urge this committee to move in this direction—and I wish you luck.

DR. EDWARD JOHNSON

Good Afternoon! My name is Ed Johnson. I am a cattleman from Parma, Idaho, with special interest, as partner/manager of Apple Valley Feedlot; and owner/manager of Johnson Research and E. G. Johnson Farms Inc. I also serve as chairman of the National Cattlemen's Association's Meat Inspection Subcommittee. The National Cattlemen's Association⁸ is an organization that serves over 230,000 cattle producers across the United States.

NCA would like to thank the Subcommittee on Agricultural Research, Conservation, Forestry, and General Legislation for the invitation to participate in today's hearing. We hope NCA's response to the subcommittee's questions will be helpful as you continue your discussions on meat and poultry inspection reform.

The subcommittee is to be commended for holding these hearings to address improvements to the Nation's meat and poultry inspection system. Let me make it very clear that NCA believes it is imperative for the consumer and the beef industry, that the meat and poultry inspection system be effective and beyond reproach. Public safety concerning our products is of paramount importance.

NCA supports the establishment of a meat and poultry inspection system that is based on scientific analysis and implemented in conjunction with a Hazard Analysis and Critical Control Points (HACCP) system and risk assessment. The current inspection system was designed primarily to eliminate diseased livestock and poultry from entering our food supply. To that end, it has been most effective in protecting consumers from diseases such as *brucellosis*, *tuberculosis*, *trichinosis* and avian influenza only to name a few. Yet this system, based on sight, smell and feel, is limited in its ability to deal with microbial hazards. It does not begin to take advantage of the technological tools available today.

NCA supports efforts to improve the meat and poultry inspection system through the proposed Track I and Track II initiatives. Program change based on solid scientific principles is the only way to improve the effectiveness of the system, eliminate political bias and achieve new heights in food safety. Implementing risk analysis through research on how and why microbiological pathogens grow and persist, and by developing management systems that allow for control and intervention, are logical and necessary steps in this process.

Since 1988, NCA has asked the USDA to improve the meat inspection system by implementing new methodologies and technology that will help both plant employees and inspectors to do a better job of assuring safe and wholesome meat products. In 1990, NCA asked that epidemiological research and risk assessments be used to develop strategies for control measures to minimize the risk of human exposure to *E. coli* 0157:H7.

Our track record shows that cattlemen take the issue of food safety seriously. The NCA Beef Safety Assurance Task Force, formed in 1986, was novel in its approach in establishing a national producer education program and network for cattlemen that continues to help assure the production of safe beef. Today the beef industry has established an industry-wide Beef Quality Assurance Programs designed to work with producers from cow-calf, stocker, and feeder operations in identifying management techniques that enhance the safety and quality of beef products.

NCA adopted policy in 1988 calling for more research on 0157:H7 and other pathogens that produce toxins in livestock and poultry. We have many questions that deal with this organism at the production level and we are aggressively sup-

⁸The National Cattlemen's Association is the national spokesman for all segments of the beef cattle industry—including breeders, producers, and feeders. The NCA represents approximately 230,000 cattlemen. Membership includes individual members as well as 46 affiliated State cattle associations and 29 national breed associations.

porting research projects with check-off dollars to expand our knowledge base. In the past 4 years alone, farmers and ranchers have invested over \$1.5 million in research to investigate *E. coli* 0157:H7, to develop test to detect this pathogen and to develop ways to manage the pathogen from farm to fork. Additionally, producers have earmarked \$1.2 million for further research in this area in 1994. Some specific projects include:

- Effect of Sodium Lactate on Microbial Safety and Consumer Acceptability of Precooked Roast Beef, Texas A&M University
- Safety Enhancement of Partially Cooked Refrigerated Meat Products, University of Wyoming
- Fate and Control of *E. coli* in Beef, University of Wisconsin
- Detection and Control of Enterohemorrhagic *E. coli* 0157:H7 in Cattle, University of Georgia
- Use of Natural Secondary Barriers to Inhibit Pathogens in Refrigerated, Cooked Roast Beef, University of Georgia
- Determine the Efficacy of Organic Acid Rinses in Reducing the Level of Microbiological Pathogens on Beef Carcasses, (USDA approved this process in 1993)
- Investigate the Effect of Cooking Practices (both conventional and microwave) on the Elimination of *E. coli* 0157:H7 and Foodborne Pathogens in Meat Cuts and Ground Beef

With each *E. coli* 0157:H7 outbreak, unanswered questions continue to rise elevating the concern and frustration of cattle producers, consumers and the scientific community. If expression of this pathogen is principally related to beef, why have we not been able to document exposure in animal handlers? Why is this organism not an evident pathogen in cattle? What are the circumstances leading to the propagation and increasing expression of *E. coli* 0157:H in the past two decades? The list of questions goes on and on.

In an effort to help find answers to many of these questions, the beef industry formed a "Blue Ribbon" panel on *E. coli* 0157:H7 in September, 1993. Representatives serving on the panel include producers, industry scientists, food microbiologists, regulatory officials, and public health professionals. They have been working diligently gathering the most recent scientific data and testimony regarding this organism. The objectives will include strategies on detection, control and intervention of this pathogen.

NCA is aware of the Departments' discussion on preharvest inspection with on-farm visits. Cattlemen are concerned with some government and industry officials who are touting to the media and consumers that on-farm testing and/or animal vaccinations are the major component of pathogen control. NCA simply asks that officials refrain from making any judgments until the scientific evidence is available. As a practicing veterinarian and researcher of animal drugs and vaccines, I question our ability to develop an animal vaccine to combat an organism that is not pathogenic to the animal we propose to vaccinate. In the meantime, please be assured that if research shows that certain production systems can be effective in controlling pathogens, we will gladly work with government officials and utilize our Beef Quality Assurance Programs to provide producer education and assistance in implementing such systems.

USDA's development and implementation of on-farm testing will depend on creating a partnership with producers. The livestock industry's successful efforts toward eradicating tuberculosis and brucellosis, through joint cooperation with the Animal Plant Health & Inspection Service, serves as a positive example and reminder of why it is imperative for producers to be involved in developing any program that involves practices at the farm level.

NCA encourages the USDA to deal with those issues that are real and not those that are only good for favorable headlines. A good example are calls for mandatory individual identification of cattle. In 1990, NCA requested and paid for a study by South Dakota State University and Texas A&M University to measure the adequacy of our current trace back system. The results were very conclusive. The current system is working well and could be further enhanced with minor improvements. Therefore, NCA would caution against exhausting precious time and resources debating, developing and implementing a mandatory identification program that would accomplish nothing more, relative to food safety, than the current system. Trace back ability to the farm or ranch of origin should be the objective, not the mandatory individual identification of animals.

USDA's public relation efforts to tout the budgeted addition of 400 inspectors in 1994 and 1995, as the Secretary's response to fighting microbiological contaminants, is giving the consumer false expectations and setting the industry and the Food

Safety Inspection Service (FSIS) up for grave criticism when the next *E. coli* 0157:H7 outbreak occurs. The establishment of HACCP systems and improved technologies will best combat microbiological pathogens. However, NCA will not dispute the need for 400 additional inspectors to bring the current inspection system up to the original standards for detecting animal disease and physical contaminants for process control. We simply ask that USDA's information be accurate in describing what the additional inspectors bring to the system.

NCA questions the effectiveness of USDA's re-issuance of the "Zero Tolerance" rule and the subsequent "hand trimming" requirement for removal of physical contaminants. Once again, touted by USDA as a crack down on industry to help combat physical and microbiological contamination, has only filled the consumer with false hope. In reality, a recently completed research project has concluded that a high-pressure (300 p.s.i.) water washing of beef carcasses is far superior in reducing pathogen contamination on carcasses than the hand trimming currently required. While we all agree and recognize that physical contaminants should be removed, let's also recognize that the additional handling of the carcasses by inspectors and plant employees and the extended exposure of the carcasses to the warm moist air of the slaughter room, also contribute to microbiological contamination. NCA points to the fallacies of the Zero Tolerance Initiative, that the industry has had to live with over the last several months, as a classic example of the Department trying to use yesterdays antiquated regulations and methods in dealing with todays problems. The only thing the Zero Tolerance initiative has accomplished to date has been an inequitable interpretation of the rule by inspectors from one region of the country to the other, giving meat packers an excuse for creating marketing disadvantages for cattle feeders.

As we move forward on inspection reform, NCA believes that we should also take advantage of the opportunity to modernize and harmonize existing meat and poultry legislation. Regulations under the Federal Meat Inspection Act of 1906 and the Poultry Products Inspection Act of 1957 have evolved separately over the last few decades leading to numerous inspection, processing, labeling, and marketing inequities between red meat and poultry products. Recently, the Research Triangle Institute of North Carolina completed a report titled *Comparison of USDA Meat and Poultry Regulations*, and submitted it to USDA for it's review. Hopefully the Department will share the original report with the subcommittee as well. NCA is hopeful that this independent third party analysis will be helpful in identifying rules and regulations that need updating to a more modern, equitable inspection system. NCA is also hopeful that the report can be used as a resource for combining the current two Acts governing the slaughtering, processing, inspection, labeling and distribution of meat and poultry into one Meat and Poultry Inspection Act.

Let me conclude by saying that cattle producers support the professional staff of FSIS and their objectives to modernize and improve the meat and poultry inspection system. As a cattle producer and member of NCA, I will continue to commit my resources to resolve food safety concerns on the farm. As a consumer, I am counting on USDA to assure the safest meat and poultry supply possible. A farm-to-table approach will require the cooperation of all participants. Command and control systems which are punitive toward the industry, will not be as effective as cooperative efforts directed toward mutually agreed upon food safety goals, even if those goals are extremely ambitious and challenging.

NCA looks forward to working with USDA in maintaining the consumer's confidence in the safety of beef products and this subcommittee as we move forward to inspection reform.

Thank you for the opportunity to participate in the hearing.

JOHN W. HARMAN

We are pleased to submit this statement on recent efforts to improve the ability of the Federal meat inspection system to prevent another outbreak of food poisoning similar to the cases in January 1993 that caused several deaths and hundreds of illnesses. You asked that we comment on the progress made by the U.S. Department of Agriculture (USDA) and its Food Safety and Inspection Service (FSIS) to prevent another outbreak caused by the specific *E. coli* bacteria responsible. More specifically, you asked (1) what changes have been implemented in the meat inspection system, (2) how effective these changes have been, and (3) what still needs to be done to provide consumers with a safe meat supply. Furthermore, GAO and other organizations have detailed the limitations of the current Federal meat and poultry inspection system in numerous reports and testimony since 1969.

In summary, while FSIS has made some changes, the inspection system is only marginally better today at protecting the public from harmful bacteria than it was a year ago, or even 87 years ago when it was first put in place. FSIS' recent efforts have neither dealt with the inspection system's inherent weaknesses nor fundamentally changed the system's reliance on sensory (sight, smell, and feel) inspection methods. These methods cannot identify microbial contamination, such as harmful bacteria, which is the most serious health risk from meat and poultry. Although FSIS has known about this problem for 15 years or more, its major initiative in response—designing and implementing a new inspection system—is still years away.

In fiscal years 1993 and 1994, USDA budgeted about \$45 million and about 440 staff years, including \$14 million and 200 staff years for additional inspectors, and put together a program of 81 projects to improve its current inspection system. FSIS' efforts include (1) proposing a regulation mandating the use of package labels describing how to handle and cook meat and poultry safely, (2) undertaking over two dozen data collection and research projects, and (3) implementing stronger oversight of meat and poultry plants with a high-risk profile. In addition, FSIS has begun a long-term effort to study how the inspection system can be completely revamped to better protect public health.

FSIS' efforts have probably lowered the chance that people will become ill from eating meat contaminated with harmful bacteria. For example, because of FSIS' efforts to provide information, consumers and retail food establishments are now more aware that raw meat products must be properly handled and cooked to control or kill bacteria. Also, FSIS' more vigorous enforcement of the current sanitation and slaughter processing regulations will indirectly help control bacterial contamination by eliminating some potential sources of contamination. However, the ability of the inspection system to detect harmful bacteria, evaluate how serious the problem is, and take corrective action remains limited. FSIS has not established a regulatory program requiring plants and inspectors to routinely test for harmful bacteria. Such testing is the only conclusive means to determine whether (1) sanitation and processing controls are working properly and (2) the product is free of contamination.

As GAO and others have repeatedly stated over the past 15 years, a new, scientific, risk-based inspection system is needed to better protect the public from foodborne illnesses. Such a system would allow FSIS to target its resources towards higher-risk meat and poultry products by increasing inspection of such products, developing methods or tools that would help inspectors detect microbial contamination, and/or increasing the testing of such products.

Before providing more detail on our findings, let us briefly give you some background on the current inspection system.

BACKGROUND

At the turn of the century, Upton Sinclair's *The Jungle* raised a public outcry about contagious animal diseases, unsanitary conditions, deceptive practices, and lax government inspection at meat packing plants. The Congress responded to this outcry by passing the Federal Meat Inspection Act in 1907. This act and a subsequent poultry act require Federal inspection of meat and poultry to ensure that they are safe, wholesome, and correctly labeled and packaged. To achieve these objectives, the acts require that each individual animal carcass be examined at the time of slaughter by an on-line USDA inspector.⁹ In this traditional inspection, largely unchanged for 87 years, inspectors make judgments about disease conditions, abnormalities, and contamination in animals and carcasses on the basis of what they see, feel, and smell—a process known as organoleptic inspection.

After slaughter, meat and poultry from Government-inspected carcasses can be inspected again during further processing. (Processing operations can include simple cutting and grinding, complex canning procedures, or the preparation of ready-to-eat products.) FSIS implements the Federal inspection laws by requiring that all meat and poultry processing plants be visited daily by a USDA inspector, who may spend from 15 minutes to several hours performing various inspection duties. These inspections, too, rely primarily on organoleptic methods.

Nevertheless, the safety of meat and poultry remains a concern. While inspectors may indirectly identify some microbial contamination using these traditional methods, they cannot see, smell, or feel the presence of microbial pathogens. FSIS and others have recognized that such pathogens now present the greatest risk to public health from eating meat and poultry. Although the actual extent of foodborne illnesses is unknown, the Centers for Disease Control estimates that there are from

⁹In fiscal year 1992, FSIS inspectors visually checked 89.2 million swine, 30.8 million cattle, 5.1 million sheep and lambs, 1.8 million other livestock, and 6.8 billion poultry.

6.5 million to more than 80 million cases annually and has recognized that meat and poultry products are a primary cause of foodborne disease. USDA estimates that the annual cost of foodborne illness in the United States ranges from \$5.2 billion to \$6.1 billion, with more than half of this amount—\$3.9 billion to \$4.3 billion—attributable to meat and poultry.

The problem of microbial contamination of meat and poultry products and its devastating consequences was evidenced in January 1993, when over 450 people became ill and several children died from causes attributed to hamburgers contaminated with a form of *E. coli* bacteria. This incident has renewed concern about the ability of the Federal inspection system to adequately protect the public from similar outbreaks of food poisoning.

FSIS HAS TAKEN INITIATIVES TO BETTER PROTECT THE PUBLIC FROM HARMFUL BACTERIA

In response to last year's tragic incident, FSIS announced a two-track plan to update the meat and poultry inspection system. Track I, currently under way, is a near-term plan for maximizing the effectiveness of the existing system. Track II, initiated in 1993, is described as a longer-term "revolutionary plan" aimed at overhauling the entire system. FSIS estimates that the modernized system developed in Track II will be in place by the year 2000.

On January 27, 1994, FSIS provided us with information on 81 individual projects undertaken as part of Track I. These projects generally fall into four categories:

—*Strengthened oversight and regulatory enforcement.* Stronger oversight of meat and poultry plants was the focus of 28 projects. For example, projects included assigning more experienced inspectors to plants that slaughter higher-risk animals; developing a profile of "problem" plants and making unannounced, special reviews of plants fitting the profile; and writing new rules to strengthen record-keeping requirements. As with FSIS' routine inspections of slaughter and processing plants, these new initiatives rely on organoleptic inspection procedures.

—*Greater consumer awareness.* Efforts to increase consumer awareness of the potential hazards of raw meat and poultry were involved in 15 projects. The most significant initiative in this category is the well-publicized proposed regulation that would mandate that all raw meat and poultry products sold at retail stores include a label on safe handling and cooking procedures. While consumer education should help reduce the number of outbreaks of food poisoning, it will not eliminate them. For example, since the *E. coli* outbreak of January 1993, the Nation has, according to FSIS' records, continued to experience biweekly incidents of foodborne illnesses caused by meat contaminated with the same *E. coli* bacteria.

—*Data collection, research, and studies.* Various initiatives to collect data, conduct research, and perform studies of microbial pathogens comprised 32 projects. These projects include national baseline studies of bacteria found on carcasses at slaughter plants, research projects to determine the cause and source of harmful bacteria, and the publishing of criteria that biotechnology firms should consider when developing quick tests for detecting microbial contamination. These initiatives could potentially help prevent foodborne illness in the long term, but in the near term do not preclude such incidents. In addition, five of these projects were undertaken by the USDA's Animal and Plant Health Inspection Service as part of a program to control *Salmonella enteritidis* in eggs.

—*Stricter procedures for slaughter and dressing.* Stricter slaughter and dressing procedures to reduce the potential for bacteria from intestinal sources to contaminate the carcass were the subject of six projects. These projects involve requiring that carcass and boneless meat surfaces be free of visible contamination. Like consumer education, these stricter procedures should help reduce the incidence of foodborne illnesses by indirectly reducing some potential sources of microbial contamination. However, they do not help inspectors directly identify microbial contamination.

FSIS INITIATIVES DO NOT HELP INSPECTORS IDENTIFY AND EVALUATE BACTERIA

While FSIS has made some constructive changes and undertaken numerous research and data collection projects, it has not yet overcome the inspection system's

inherent weaknesses nor made the fundamental changes needed to better protect the public from the most serious health risk from meat and poultry—microbial contamination.

With advances in animal and veterinary science, many infectious diseases have been controlled, thereby decreasing the human health hazard posed by animal diseases. In contrast, microbial hazards associated with the crowding of animals and other factors have grown. FSIS clearly recognized this change in risk in its 1991 report to the Congress. According to that report, microbial hazards present the greatest risks posed by meat and poultry to public health.

None of the 81 FSIS initiatives undertaken under Track I have changed the labor-intensive, organoleptic process used at meat and poultry plants. During visits to meat and poultry plants, we watched inspectors using knives, flashlights, mirrors, and thermometers. While inspectors may identify some contamination using these traditional methods and tools, they cannot see, feel, or smell microbial pathogens. As a result, the current inspection system cannot protect consumers from today's most serious food safety risk—pathogenic microorganisms like *E. coli*.

Among the limitations of the current inspection system that we have addressed in our body of work, we would like to highlight two that are especially relevant in our assessment of FSIS' efforts in the past year to strengthen its inspection system. First, current laws restrict FSIS' flexibility to respond to changes in the level of risk. Regardless of the risk to public health, FSIS is required by law to perform continuous inspection at slaughter plants—examining every carcass—and to visit each processing plant daily. Because of these requirements, the Agency is limited in its ability to adjust inspection frequencies and target its resources to respond to changing risk.

Second, although FSIS has known for many years that microbial contamination was a serious problem, it has not routinely performed microbial tests of equipment surfaces or raw products, nor does it require industry to perform such tests. As a result, FSIS does not know where in the production and processing cycle microbial contamination is most likely to occur, or what types of bacteria are prevalent and at what levels. Such information is needed to design and implement an effective control program. FSIS now recognizes the need for such information and has initiated various research and data collection efforts.

Nevertheless, some plants also recognize the importance of microbial testing. They have already established their own testing programs to identify microbial contamination and have taken corrective actions based on the results. For example, one plant we visited started a microbial testing program to check on the effectiveness of its cleaning procedures. Test results indicated that even though cleaned surfaces had passed FSIS' inspection, some surfaces still contained high levels of bacteria. Company management therefore revised the cleaning procedures to reduce bacteria levels. However, FSIS has not provided leadership by developing industrywide guidelines or standards that define a safe level of bacteria to help those plants that do perform microbial tests, nor has FSIS attempted to collect or disseminate the results of these programs to help other plants correct similar problems.

SCIENTIFIC, RISK-BASED INSPECTION SYSTEM IS NEEDED

Although experts agree that the intensity and type of inspection should be determined by the risk a particular food presents, the current meat and poultry inspection system is not based on risk and is not able to adequately protect the public from foodborne illness. Labor-intensive inspection procedures and inflexible inspection frequencies drain resources that could be put to better use in a risk-based system.

Shortly after the *E. coli* poisoning incident, in testimony in March 1993, we said that to protect the public from unsafe meat and poultry, FSIS needs to move to a scientific, risk-based inspection system. Such a system would allow FSIS to target its resources towards the higher-risk meat and poultry products by increasing the inspection of such products, developing methods or tools that would help inspectors to detect microbial contamination, and/or increasing the testing of such products.

One concept for improving the scientific basis for regulating food safety is a production control process known as Hazard Analysis and Critical Control Point (HACCP). This process consists of identifying the likely hazards that could be presented by a specific product and then identifying the critical control points in a specific production process where a failure would likely result in a hazard being created or allowed to persist. These critical control points are then systematically monitored, and records are kept of that monitoring. Corrective actions are also documented.

On May 27, 1993, the Secretary of Agriculture directed FSIS to publish in 90 days a plan for carrying out his decision to mandate that all meat and poultry plants

set up HACCP systems. However, even though USDA has been actively pursuing HACCP for 3 years, FSIS has not yet proposed any regulations, decided on specific requirements for plant HACCP systems, or decided on whether it will require microbial testing to monitor or verify a system's performance.

To achieve fundamental changes in the Federal meat and poultry inspection system, we recommended in March 1993 that FSIS (1) develop and implement a clear and detailed plan for change, (2) obtain a consensus for change by soliciting the involvement of all interested parties, and (3) seek legislative changes to the meat and poultry inspection acts and congressional guidance on the objectives of the Federal inspection system.

In its response to our recommendations, USDA told us that actions were under way to respond to the first two recommendations but that it had no plans to advance extensive legislative proposals until it completed a series of public hearings.

CONCLUSIONS

A year after the *E. coli* outbreak, the present inspection system cannot identify and prevent meat contaminated with pathogenic bacteria like *E. coli* from entering the Nation's food supply. It still relies primarily on organoleptic inspection procedures that are not capable of detecting such pathogens—the greatest public health risk associated with meat and poultry. FSIS' initiatives to improve the inspection system have not addressed this inherent weakness, nor has FSIS sought requirements for routine microbial testing by industry or government inspectors.

To better protect the public from foodborne illnesses, FSIS must move to a modern, scientific, risk-based inspection system. Such a system would allow FSIS to target its resources towards the higher-risk meat and poultry products by increasing inspection of such products, developing methods or tools that would help inspectors detect microbial contamination, and/or increasing the testing of such products.

This completes our prepared statement. We will be glad to discuss meat and poultry inspection issues further with you, other subcommittee Members, or your staffs.

GENERAL ACCOUNTING OFFICE AND OTHER REPORTS SINCE 1969 ON THE FEDERAL MEAT AND POULTRY INSPECTION SYSTEM

GAO Reports

Food Safety: A Unified, Risk-Based System Needed to Enhance Food Safety (GAO/T-RCED-94-71, Nov. 4, 1993).

Food Safety: Building a Scientific, Risk-Based Meat and Poultry Inspection System (GAO/T-RCED-93-22, Mar. 16, 1993).

Food Safety: Inspection of Domestic and Imported Meat Should Be Risk-Based (GAO/T-RCED-93-10, Feb. 18, 1993).

Food Safety and Quality: Uniform, Risk-based Inspection System Needed to Ensure Safe Food Supply (GAO/RCED-92-152, June 26, 1992).

Food Safety and Quality: Salmonella Control Efforts Show Need for More Coordination (GAO/RCED-92-69, Apr. 21, 1992).

Food Safety and Quality: FDA Needs Stronger Controls Over the Approval Process for New Animal Drugs (GAO/RCED-92-63, Jan. 17, 1992).

U.S. Department of Agriculture: Improving Management of Cross-Cutting Agricultural Issues (GAO/RCED-91-41, Mar. 12, 1991).

Food Safety and Quality: Who Does What in the Federal Government (GAO/RCED-91-19A&B, Dec. 21, 1990).

Food Safety and Inspection Service's Performance-Based Inspection System (GAO/T-RCED-89-53, July 31, 1989).

Internal Controls: Program to Address Problem Meat and Poultry Plants Needs Improvement (GAO/RCED-89-55, Mar. 31, 1989).

Imported Meat and Livestock: Chemical Residue Detection and the Issue of Labeling (GAO/RCED-87-142, Sept. 30, 1987).

Inspection Activities of the Food Safety and Inspection Service (GAO/T-GGD-87-15, May 15, 1987).

Compendium of GAO's Views on the Cost Saving Proposals of the Grace Commission, Vol. II—Individual Issue Analyses (GAO/OCG-85-1, Feb. 19, 1985).

Monitoring and Enforcing Food Safety—An Overview of Past Studies (GAO/RCED-83-153, Sept. 9, 1983).

Improved Management of Import Meat Inspection Program Needed (GAO/RCED-83-81, June 15, 1983).

Improving Sanitation and Federal Inspection at Slaughter Plants: How to Get Better Results for the Inspection Dollar (CED-81-118, July 30, 1981).

A Better Way for the Department of Agriculture to Inspect Meat and Poultry Processing Plants (CED-78-11, Dec. 9, 1977).

Selected Aspects of the Administration of the Meat and Poultry Inspection Program (CED-76-140, Aug. 25, 1976).

Consumer Protection Would Be Increased By Improving The Administration of Intra-state Meat Plant Inspection Programs (B-163450, Nov. 2, 1973).

Consumer and Marketing Service's Enforcement of Federal Sanitation Standards at Poultry Plants Continues to Be Weak (B-163450, Nov. 16, 1971).

Need To Reassess Food Inspection Roles Of Federal Organizations (B-168966, June 30, 1970).

Weak Enforcement of Federal Sanitation Standards at Meat Plants by the Consumer and Marketing Service (B-163450, June 24, 1970).

Enforcement of Sanitary, Facility, and Moisture Requirements at Federally Inspected Poultry Plants (B-163450, Sep. 10, 1969).

USDA Office of Inspector General Reports

Food Safety and Inspection Service: Monitoring of Drug Residues (Audit Report No. 24600-1-At, Sept. 30, 1991).

Food Safety and Inspection Service: Labeling Policies and Approvals (Audit Report No. 24099-5-At, June 1990).

Food Safety and Inspection Service: Follow-Up Audit of the Imported Meat Process (Audit Report No. 38002-4-Hy, Mar. 29, 1989).

Food Safety and Inspection Service: Audit of the Imported Meat Process (Audit Report No. 38002-2-Hy, Jan. 14, 1987).

Food Safety and Inspection Service: Meat and Poultry Inspection Program (Audit Report No. 38607-1-At, Sept. 26, 1986).

Studies by the Congress, Scientific Organizations, and Others

Meat and Poultry Inspection: Background and Current Issues (Congressional Research Service, Report No. 93-574 ENR, June 9, 1993).

Setting the Food Safety and Inspection Service on a Path to Renewal (report of USDA's Management Evaluation Team, Nov. 1991).

Cattle Inspection (Food and Nutrition Board, Institute of Medicine, National Academy of Sciences, 1990).

Federal Poultry Inspection: A Briefing (Congressional Research Service, Report No. 87-432 ENR, May 8, 1987).

Food Safety Policy: Scientific and Regulatory Issues (Congressional Research Service, Order Code IB83158, Feb. 13, 1987).

Poultry Inspection: The Basis for a Risk-Assessment Approach (National Research Council, National Academy of Sciences, 1987).

Meat and Poultry Inspection—The Scientific Basis of the Nation's Program (National Research Council, National Academy of Sciences, 1985).

Food Safety Policy Issues (Congressional Research Service, Report No. 81-155 SPR, June 1981).

Study on Federal Regulation, Regulatory Organization (Committee on Governmental Affairs, U.S. Senate, vol. V, Dec. 1977).

Study of the Federal Meat and Poultry Inspection System (Booz, Allen, and Hamilton, Inc., June 1977).

DR. JAMES H. DENTON

The Council for Agricultural Science and Technology (CAST) represents 26 professional societies involved in the science and technology of food production, processing and marketing. The membership in these organizations includes professionals in research, teaching, extension education, government agencies and health organizations. The expertise provided by these professionals is the combination of extensive careers spent in developing and improving the U.S. food supply. It is my privilege to offer these comments on their behalf.

In March 1993, I appeared before the joint hearing of the Agriculture Subcommittee on Department Operations and Nutrition, and the Subcommittee on Livestock of the U.S. House of Representatives to testify regarding what was viewed as a failure in the Meat and Poultry Inspection system of the Food Safety and Inspection Service (copy attached)¹⁰. USDA-FSIS Administrators and staff at that time were embarking upon a course to modernize the Meat and Poultry Inspection System. Two major strategies to achieve these goals were presented, the Pathogen Reduction Program (March 1993) and the Evolution to Revolution FSIS Strategic Plan (May 1993) outlining several objectives. The comments provided below will address three primary areas:

1. Changes, or action items, which have occurred
 2. Evaluation of the overall effectiveness of the plan
 3. Proposed direction, action agenda, for the future
- The National Advisory Committee for Meat and Poultry Inspection

During April, 1993 it was my privilege to participate in the deliberations of the NAC-MPI during which several items of urgency to the issue of improved inspection systems were discussed in addition to the proposed safe handling label and the implementation of HACCP based inspection systems. The consensus of the committee was that HACCP based inspection, founded in sound science, was an effective approach to modernizing the inspection system although the issue of mandatory *vs.* voluntary implementation was a major point of divergence among the group. However, all participants in the committee discussions agreed that the implementation of HACCP based inspection requires a significant commitment to employee education for the meat and poultry industries and regulatory agencies alike.

- National Educational Forum for Food Safety Issues (NEFFSI)

Based upon the stated objectives of the Pathogen Reduction Program to provide science based education for foodservice and consumer clientele groups, the executive committee of NEFFSI provided summary briefings of successful, locally based education programs targeted to food service audiences for the Administrators of FSIS, Dr. H. R. Cross; ES, Dr. M. Johnsrud; as well as Secretary of Agriculture, Mike Espy. The success of the program is based on the commitment of the Cooperative Extension Service County Home Economist and the local Health Department Sanitarian, with the support of the Food Science specialist of the land-grant universities (Virginia Polytechnic Institute, Kansas State University, University of Arkansas, as examples) and the education materials provided by the Educational Foundation of the National Restaurant Association. An agreement, in principle, to the value of education involving USDA-FSIS, CES, FDA and EF-NRA was recommended by NEFFSI as a primary strategy to meet the stated objectives.

- Regional Hearings Conducted by FSIS

The FSIS conducted six regional hearings to receive input regarding the Pathogen Reduction Program and the Evolution to Revolution—FSIS Strategic Plan from constituents across the U.S. These hearings provided valuable insight into the very diverse opinions and level of understanding for many groups involved in the meat and poultry inspection system. The key point reinforced in these comments is the need for more extensive education regarding the complex issues involved in meat and poultry safety for both industry and consumers alike.

- World Congress on Meat and Poultry Inspection

The FSIS also conducted a World Congress on Meat and Poultry Inspection in which it was my privilege to participate. Representatives from 12 countries worked collaboratively in addressing issues of common concern including HACCP implementation, microbial criteria, guidelines and standards and other complex issues. In the global market of today it is imperative that open dialogue involving scientists and regulators from all trading partners be conducted. The issue of food safety in

¹⁰ Testimony is retained in Committee files.

international trade must be addressed on the basis of sound science and with effective education. This also contributes to a safer utilization of the meat and poultry supply.

- Conference on Regulatory Program of the Future

Another stated objective of the FSIS Strategic Plan was to obtain input, and where possible consensus, from the groups and organizations who have a stake in devising the new meat and poultry inspection system. This monumental undertaking was accomplished by the commitment and vision of Dr. Cross and the staff at FSIS. It was also my privilege to participate in these discussions in the attempt to be part of the solution to modernizing the meat and poultry inspection system. Although there were some points of consensus; (1) the value of education in food safety program, (2) food safety as a continuum from the farm to the table, (3) HACCP as an effective management tool to assist in assuring food safety, there were points where consensus was not obtained, and probably should not due to honest differences of opinion. However, it was a necessary step to complete in order to place the Strategic Plan in motion.

- Industry and University Response

The incorrect impression exists that the meat and poultry industries are not responsive to consumer concerns regarding food safety. This is unfortunate at best when industry is portrayed as motivated by profit only, with safety and quality not being an important part of their company mission. Food companies in today's market have a greater amount at risk, their reputation and economic well being, than at any time in the past.

The following is a partial list of organizations which have a long standing tradition of providing education and training for their membership, some of which have developed and implemented HACCP Training Programs (I apologize in advance for omission of any organizations/universities with active programs).

American Meat Institute—working with Kansas State University and Iowa State University

Southeastern Poultry and Egg Association, National Broiler Council, National Turkey Federation—working with University of Arkansas, Virginia Polytechnic Institute, University of Georgia, North Carolina State University

Educational Foundation of the National Restaurant Association—working with Virginia Polytechnic Institute, University of Arkansas, Kansas State University, University of Puerto Rico, as well as many of the hospitality schools and community colleges around the country

Klenzade Corporation (Division of Ecolab)—working with Virginia Polytechnic Institute, University of Arkansas, Kansas State University, California Polytechnic State University, South Dakota State University

ABC Labs—working with Southeastern Poultry and Egg Association

Food Processors Institute

Food Marketing Institute

The key point is that many of these groups have education activities as long as 15 years in duration. Although HACCP training is relatively recent (1987) for some of them, the QA/QC training efforts which were the predecessors of HACCP are not new. The commitment to improved safety has been a primary goal of the meat and poultry industries long before it was fashionable to be concerned about food safety.

Summary

- The FSIS has met the stated objectives outlined in the FSIS Strategic Plan for having initiated the modernization of the meat and poultry inspection system. The Pathogen Reduction Program objectives are more long term and will require a much greater effort.

- The statement that the outbreak of the *E. coli* 0157:H7 foodborne illness represents a failure in the inspection system is not correct. Even with the decision to enforce "zero tolerance" for fecal contamination on carcasses, it is not the same as "zero contamination". All *raw meats* and *poultry* will have bacteria present, and therefore can potentially have pathogens present. To imply otherwise is to mislead the consumer to believe raw meats are "sterile" and do not require proper handling during storage and preparation.

- The time has come for producers, processors, distributors, food service operators, food retailers, consumers and food regulators to recognize that they are not

adversaries but rather are *equal partners* in the solution to food safety concerns. Correct handling practices at all stages of the marketing system and the adoption of HACCP principles at all levels will lead to an improved level of safety in the meat and poultry supply.

- Given the current situation regarding the food production, processing and marketing system, education of workers from farm to table, and including consumers, appears to provide the greatest opportunity to truly improve the safety of the meat and poultry supply.

- While there is no need to apologize for the safety of the meat and poultry supply, there is always room for improvement of the entire system. This has been and continues to be the goal of all concerned in the marketing system.

Mr. Chairman, I thank you for the opportunity to provide these comments, and hope that they will prove useful in your committee's deliberations.

DR. JERRY R. GILLESPIE

Mr. Chairman, and Members of the subcommittee, I am pleased to have this opportunity to present a statement on behalf of the Food Animal Production Medicine Consortium (FAPMC)¹¹. We acknowledge and appreciate the committee Members' interest in improving human health, sustaining agricultural resources, and improving agricultural's long-term competitiveness and profitability by exploring new ways to improve our current food inspection programs.

PRE-HARVEST FOOD SAFETY: A PRACTICAL AND EFFICIENT APPROACH TO LIMITING OR ELIMINATING BIOLOGICAL AND CHEMICAL CONTAMINATION OF FOOD

The FAPMC represents faculty and staff from six land-grant universities¹² who joined together in 1988 to improve the quality and efficiency with which we address our universities' missions: (1) veterinary education in the area of food animal medicine, food safety and public health, (2) on-farm food safety research, (3) animal health and natural resource management research, and (4) clinical service to animal agriculture. These missions are interdependent, and our overall task is to improve food safety, reduce the incidence and cost of animal diseases, preserve natural resources and help build a sound economic base for animal agriculture. The FAPMC's teaching programs and joint research programs have been extraordinarily successful because of the diverse animal agriculture served by these universities and the combined strength of their faculties.

Members of FAPMC have been developing the concept of preharvest food safety since 1985.

I wish to say at the onset that the proposals for research, education and implementation of improved on-farm practices encompassed in the preharvest food safety principles are consistent with Track II proposed in 1993 by FSIS. These principles are presented in more depth in the FAPMC's publication, *Providing Safe Food for the Consumer, A Blueprint for implementing Preharvest Food Safety Internationally*,¹³ which is being distributed to Members of the subcommittee.

Recognizing that most contamination of food animals by potentially harmful chemicals or microbiological agents originates on farms, we have designed model management programs to limit contamination of animals or food products prior to their leaving the farm gate of privately owned "core farms" in each of the six States. Working with practicing veterinarians and producers, specialists from our faculties use computer-based, comprehensive management programs that systematically examine control strategies for contaminants at Critical Control Points (CCP) on the farm and during transport of food-products to processing plants. Our initial on-farm tests include beef, veal, pork, dairy, sheep and poultry production units in the six States, and each has achieved improvement in production practices leading to better quality assurance for products leaving these core test farms and at substantial savings and greater profits for producers.

We are convinced that vast improvements can be made very soon in food safety by implementing our current analysis and management programs. To expand the use of this new management technology will require a substantial effort to educate veterinary specialists at other institutions, practicing veterinarians, producers and others involved in food production during the preharvest phase. While our innova-

¹¹ FOOD ANIMAL PRODUCTION MEDICINE CONSORTIUM (FAPMC) University of California-Davis, University of Florida, University of Illinois-Urbana-Champaign, Kansas State University, Michigan State University, and University of Nebraska-Lincoln.

¹² Ibid.

tions have focused on food animal production units, we believe similar strategies can also be used for vegetable and food-grain production units.

There is a need for much more preharvest food safety research, education and technical transfer. This is an area that has not been adequately funded considering its potential payoff for the food industry and the consumer. I will mention only a few examples of projects that in our view should have high priority for funding:

Ecology of human pathogens on food-producing farms

A comprehensive study of the ecology and control of *Escherichia coli* 0157:H7 in food animals on the farms. This study of *E. coli* should serve as a template for control of other human pathogens such as *Salmonella*, *Campylobacter*, *Listeria monocytogenes*, *Cryptosporidium* sp, or *Yersinia* to name a few. Well designed epidemiological studies which have the capacity to simultaneously evaluate impact of multiple variables will be required to fully understand the ecology of these organisms on farms.

Rapid On-Farm Detection Technologies

Investigation of rapid testing techniques for on-farm detection of *E. coli* 0157:H7 and other organisms. For example, there are DNA-probes that will detect specific strains of *E. coli*. and probes exist for other pathogenic microorganisms which may be of use to screen for these organisms in the proposed on-farm epidemiology studies.

Hazard Analysis Critical Control Points on Farms

A study to identify those environmental and/or the management factors that favor or lead to the occurrence and persistence of *E. coli* 0157:H7 (or other pathogenic organisms) in food animals. These studies could use the *Hazard Analysis Critical Control Point* (HACCP) approach on the test farms. We envision this study will involve the professional staff of several agencies within USDA (FSIS, APHIS [NAHMS], CES, and ARS), EPA and FDA, and representatives from the private sectors of agriculture.

Nation-wide Shared Data

The development of a nation-wide shared computer-based, data-management system for collection analysis of on-farm information that impacts on food safety and environmental practices. This data-base will provide investigators and others access to advance technology and information more rapidly, and reduce unneeded redundancy in preharvest food safety investigations.

Outcome Assessment

We believe these studies (and others) should include evaluation of their impact on improving food safety, sustaining agricultural resources, improving consumer safety and satisfaction, and improving long-term profitability in the agricultural sector.

These research efforts should be coordinated with efforts to introduce and implement on-farm, management practices that will reduce or eliminate *E. coli* 0157:H7 and other pathogenic organisms from food animals prior to leaving the farm gate. This can be done with a coordinated program operated by land-grant universities in cooperation with USDA Agencies, producers, commodity groups, veterinary college faculties, practicing veterinarians, Cooperative Extension Service and others. The goal should be to form an information network to provide new information on food safety issues which will lead to improved practices of producers, public health officers, consumers and others involved in the production and processing (preparing) of food. We envision the use of core-farms as demonstration units for this education and implementation effort.

Mr. Chairman, the National Research Council (1985) concluded "that the most effective way to prevent or minimize hazards presented by certain infectious agents and chemical residues in meat and poultry is to control these agents at their point of entry into the food chain, i.e., during the production phase on the farm and in feedlots."

Historically, public health officers have repeatedly demonstrated that preventative medicine is the most effective and economical approach to managing or eliminating diseases. We believe these principles apply to addressing the problem of food-borne illnesses. We urge there be \$6 million appropriated in the FY-95 budget to address the research and education initiatives in the area of preharvest food safety. This approach will provide benefits for the producer, processor and consumer, and potentially reduce the high cost of food-safety monitoring at the postharvest (processing) steps in the food chain.

Thank you, Mr. Chairman.

DR. MICHAEL P. DOYLE

I am a professor of food microbiology at the University of Georgia, and have dedicated my career to the study and development of methods to detect, control and eliminate harmful bacteria in foods. Much of my research has focused on bacterial pathogens present in meat and poultry.

Foodborne disease is no small matter in the United States. Present estimates indicate that more than one in ten Americans experience some form of foodborne illness each year and that more than 9000 deaths are linked to eating contaminated foods. Estimated cost to the U.S. economy is about \$5 billion annually.

More than 90 percent of these illnesses are caused by harmful microorganisms. Two of the most common types, salmonellosis and *Campylobacter* enteritis, are principally spread by foods of animal origin, as is the dreaded *E. coli* 0157:H7 that recently received national attention through a major outbreak in the Northwest.

Statistics maintained by the Centers for Disease Control and Prevention indicate that the cases of salmonellosis continue to increase. Many factors are thought to be responsible for this continuing trend, including: (1) greater abuse of foods by consumers and food handlers who are not aware of the hazards that exist; (2) greater consumer interest in "healthful" foods, which includes eating foods of animal origin raw or undercooked; (3) larger populations of patients receiving medication that suppresses their ability to combat foodborne infectious agents; (4) a possible increase in the occurrence of foodborne pathogens; (5) the occurrence of "new" types of bacterial pathogens; and (6) a continuing increase in the elderly population.

Programs most likely to have the greatest impact on the microbiological safety of food are those that focus on reducing, controlling, and (where possible) eliminating pathogens in foods of animal origin. The approaches presented by the U.S. Department of Agriculture's Food Safety and Inspection Service in its "War on Pathogens" are well founded and, if properly executed, should lead to major reductions in foodborne illness. However, specific and detailed strategies for implementing this program have not been provided. Hence, it is not possible to discern how the "War on Pathogens" will be integrated into the Federal Meat Inspection Program.

For the USDA Meat Inspection Program to have a major impact on decreasing meat- and poultry-borne illness, special emphasis should be placed on the following areas:

1. *Risk analysis, management, and communications.* Regulatory agencies are not likely to be able to regulate pathogens out of all foods; an alternative is to regulate on the basis of risk. Many foods, especially those of animal origin, carry with them an inherent risk because of the occurrence of microbial pathogens. Some pathogens, such as *Listeria monocytogenes*, are frequently consumed, but only cause illness in a very small segment of the population. It is not reasonable to mandate a zero tolerance of *L. monocytogenes* in all foods because of the widespread occurrence of the organism and the infrequency of the illness it causes. A risk assessment approach is needed to address this issue. Information is needed to identify the foods most frequently associated with illnesses, to identify the minimum infectious dose of harmful microorganisms, to determine the survival and growth characteristics of pathogens in foods, and ultimately to determine what levels of pathogens may or may not be tolerable in different foods.

2. *Development of innovative approaches to produce pathogen-free foods from animals.* Animals often carry microbial pathogens within their intestinal tract and on hide, skin, feathers, and feet. With the frequent occurrence of internal and external contamination by harmful microorganisms, present-day slaughter and primary processing procedures cannot reliably produce pathogen-free raw foods. Innovative, practical approaches, such as the use of probiotics or competitive exclusion, are needed to reduce the conveyance of pathogens by animals.

3. *Research to support the implementation of effective Hazard Analysis Critical Control Point (HACCP) Programs.* The HACCP approach to producing and preparing safer foods is conceptually well based and scientifically sound. However, two important needs reduce the potential of HACCP for controlling or eliminating foodborne pathogens in many food processes. These needs include:

- Real-time procedures for detecting and isolating pathogens in the environment of food processing facilities. The present one- to four-day procedures for isolating pathogens take too long. Tests that can be completed within minutes or hours would enable processors to take quick corrective action when pathogens are detected.

- Definitive kill steps that can be applied at critical control points to insure that pathogens are destroyed. Innovative, practical methods that can be effectively used in food-processing facilities are sorely needed.

4. *Develop innovative approaches to educate consumers and food preparers in proper foodhandling practices.* The incidence of salmonellosis, which is principally transmitted by foods, has increased dramatically during the past three decades. Several approaches have been taken to educate food handlers and consumers about proper food-handling practices, yet the occurrence of foodborne illness continues unabated. Reducing the incidence of foodborne disease is a challenge for the future, with a principal problem being the improper handling of foods by consumers and those involved in commercial food preparation. Innovative approaches to educating consumers and food preparers about proper food preparation techniques are needed. In addition, consumers must be made aware of the risks of foodborne illness from eating raw or undercooked foods of animal origin.

These are the issues that should receive the greatest attention and if properly addressed would have the greatest impact on reducing foodborne disease. Unfortunately, very little progress has been made in these areas during the past year, with the possible exception of consumer education by requiring the use of safe handling labels for fresh meat and poultry. Very little attention has been placed on prevention of transmission of meat- and poultry-borne pathogens, especially at the farm. Rather much of the emphasis of the meat inspection program has been placed on traceback and end product testing. These are not very productive approaches to reducing foodborne illness because traceback procedures only identify where infected animals originated which may not be meaningful if the pathogen is widely distributed in animal populations. End product testing is not very useful because pathogens are not usually uniformly distributed in meat, hence contaminated meat is likely to go undetected in many instances. It would not be practical to test all of the meat needed to assure pathogen detection.

The USDA meat inspection program should be refocused to preventing pathogen contamination of meat and poultry. This would have a much greater impact on reducing foodborne disease than the existing inspection system.

KARL JOHNSON

Mr. Chairman, and Members of the subcommittee: My name is Karl Johnson, and I serve as the president of the National Pork Producers Council (NPPC). On behalf of the council, I am pleased to have this opportunity to share our views on the progress in reforming the U.S. Department of Agriculture's Federal meat and poultry inspection program. NPPC represents approximately 85,000 pork producers through 45 State affiliates. Our members account for more than 90 percent of this Nation's pork production.

We believe the subject matter of the hearing is extremely timely as we continue to look for ways to enhance the safety of our food supply. At our annual meeting just a year ago, our delegate body approved a resolution supporting any necessary changes in the current meat inspection system to further ensure that our consumers are receiving the safest pork supply the world can offer.

To accomplish this objective, we must base any changes on the best science available. We also know that it is not economically possible to test every single piece of meat that is offered to the consuming public, so we will have to implement an efficient and effective inspection process that provides for an optimal level of testing.

I view food safety from two aspects—as a producer of food and as a consumer. As a producer of food that my family and other families eat, I want to make sure that we do everything possible to provide a safe product beginning on my farm all the way to the consumer's fork. I do not feel that my responsibilities have ended when my hogs leave my farm gate. As a consumer of meat products purchased at retail outlets, I also want to be confident that all segments of the food chain, including my fellow producers are doing their part to provide a safe, wholesome product.

U.S. pork producers have long understood the importance of producing a product in which our domestic and international consumers could have the utmost confidence. We believe USDA's Food Safety and Inspection Service (FSIS) on-going reputation as a modern, science-based agency is of critical importance.

We are operating in a global market and our system for food safety must be acknowledged by our current and potential export market customers as at least equivalent to theirs, if not the best in the world. At the same time we are reexamining our own system of meat inspection, we must continue to be vigilant in ensuring that meat produced and/or processed in other countries and imported to the United States is in compliance with U.S. standards of inspection.

Progress in Reform of Meat and Poultry Inspection Programs

We are encourage by the resolve of Secretary of Agriculture, Mike Espy, in addressing the complex area of reforming the current meat and poultry inspection system. The Department of Agriculture's two-track approach" will afford us the opportunity to make significant advances in implementing a truly science-based meat and poultry inspection system.

Substantial progress has been made over the last year in gathering information that will assist our efforts to make meaningful changes in the current inspection system. FSIS has held six public hearings allowing all constituents the opportunity to comment on FSIS's Strategic Plan and Pathogen Reduction Program. In addition, both documents were open for comment through the FEDERAL REGISTER. The "World Congress on Meat and Poultry Inspection" held in October also allowed other countries to discuss their ideas for improvements in meat and poultry inspection.

The "Conference on Regulatory Programs of the Future" provided an opportunity for all constituents to again review the current progress and provide suggestions for the continued development of the new system. In addition, USDA's upcoming Heard Analysis and Critical Control Point (HACCP) roundtable will provide an opportunity for experts to discuss the actual design and implementation of this approach to meat and poultry inspection.

Moreover, FSIS has instituted a Risk Analysis Program and obtained research authority that will be critical to directing research on high priority areas for the agency. The development of rapid detection tests for the presence of potential pathogens is one of the tools that will aid meat packers and processors in implementing and vexing their HACCP systems. FSIS has published their criteria for these types of tests in the FEDERAL REGISTER. To provide better insight into the public health aspects of foodborne illness prevention and detection, FSIS has stationed a representative at the Centers for Disease Control and Prevention as well as developing a Public Health Program.

From our perspective, these are extremely positive, necessary steps in developing a risk-based, scientifically sound meat and poultry inspection system.

Current Food Safety System

There is no question that the routine detection of potential pathogens on raw meat or poultry products is beyond the scope of the present inspection system. The system currently in use was designed to be an organoleptic inspection that detected abnormalities that are now less common in animal agriculture today. The current system does a good job with antemortem inspection of only allowing healthy animals to enter the food chain. The postmortem inspection functions to detect abnormalities of public health significance. However, FSIS has recognized that additional changes and enhancements are necessary to modernize the current system to one based on potential risks and current scientific technology.

Optimal Federal Food Safety System

The optimal food safety inspection system should be based on the best science available and a prioritization of the public health risks. Baseline microbiological studies are a critical step to determine the potential problems and identify the most likely critical control points.

HACCP should be the centerpiece of any program designed to modernize the U.S. meat inspection system. Controlling, monitoring and verifying processing systems is clearly more reliable and better able to ensure the safety of a product than reliance on end-point testing. There obviously needs to be appropriate flexibility to concentrate resources where potential public health problems exist. This also means that FSIS needs to verify that HACCP plans are being followed.

Research will continue to be a key component of a food safety system to allow continuous improvements to be made. Much more needs to be known about the epidemiology of potential human pathogens on-farm and throughout the food chain. At the same time, we must also strive to be early adopters of technological advances that will enhance food safety.

In addition, public education needs to be part of any system. Educational programs for all segments of the food chain on their responsibilities and role in maintaining the safety of the food supply is fundamental.

We believe there are insufficient resources to monitor for foodborne illness, to conduct epidemiological investigations of suspected foodborne outbreaks, and to collect and distribute timely reports to key participants in the food chain. This information is not only necessary to provide feedback to the stakeholders with responsibility for

implementing an improved meat inspection system, but to prioritize where scarce government resources should be directed in the future.

Use of Technology

It is critical that we strive to be early adopters of technological advances. New technology, such as organic sprays should quickly be made available for commercial use after being shown to be safe and effective. We also need to make use of existing technologies to enhance the safety of our food supply.

Food irradiation is one such technology that has been recognized as a safe and proven technology by over 30 countries in the world. Low-level irradiation certainly deserves another look as an option to destroy pathogens. In 1987, irradiation of pork was approved at a level of 1 kiloGray or less. This was followed in 1992, with USDA's approval for irradiation of poultry at levels up to 3 kiloGrays for treatment of *salmonella*. In looking for ways to reduce pathogens, irradiation is a tool that demands consideration.

USDA as Lead Agency in Meat and Poultry Inspection

For several reasons, we support the continuation of USDA serving as the lead agency on meat and poultry inspection. USDA is currently implementing a number of new progressive food safety approaches and programs that will improve our Nation's system of meat inspection. Such efforts should not be delayed or disrupted by an unnecessary movement or transfer of functions from one agency to another.

In addition, with the emphasis on approaching food safety with a "farm to table" approach, USDA has the experience and the tools to work most effectively with everyone from the farmer to the consumer to ensure the safety and wholesomeness of our meat and poultry products. For example, the Animal and Plant Health Inspection Service has the on-farm background and through other programs has developed working relationships with farmers that will be useful in the preharvest food safety area.

We do not believe any other agency in the Federal Government is more capable of making the necessary modifications in our meat inspection system than USDA's Food Safety and Inspection Service. USDA is truly in the best position to verify the integrity and safety of our meat and poultry supply throughout the continuum of the food chain.

Conclusion

Mr. Chairman, we commend you for your longtime commitment to, and active participation in reviewing the laws governing meat and poultry inspection to ensure that they result in the delivery of products that meet the expectations of the American consumer, whether produced or processed domestically or overseas. We believe the current public attention on food safety concerns provides us with a tremendous opportunity to make significant advances in implementing a truly science-based meat and poultry inspection system.

The National Pork Producers Council appreciates the opportunities we have had to participate in the development of strategic plans and programs to address food safety concerns. Pork producers are ready to do their part to address their responsibilities in providing a safe and wholesome product to consumers.

DR. EDWARD L. MENNING

REINVENTING THE FOOD SAFETY SYSTEM—U.S. DEPARTMENT OF AGRICULTURE'S
(USDA) PROGRESS IN REFORMING MEAT AND POULTRY INSPECTION

Background

The National Association of Federal Veterinarians has a membership of approximately 1500 veterinarians of which over 900 are employed by the Food Safety and Inspection Service (FSIS) of the United States Department of Agriculture (USDA) as experts in the general area of public health, and specifically in the field of food hygiene. They provide the professional medical services, supervision and management of FSIS programs for the antemortem and postmortem inspection of all food animals, and the inspection of some meat and meat products prepared therefrom. The men and women who are the FSIS veterinarians are dedicated public servants who are sincerely concerned that any changes in the Nation's food hygiene programs be made in the best interest of the health, nutrition and economic welfare of the public.

Well meaning spokespersons and persons with hidden agenda state that U.S. citizens enjoy the safest, most affordable and most abundant meat and poultry supply in the world. That statement may be largely true. However, the same meat and poultry annually results in illnesses of many thousands of Americans and deaths of some. There is, indeed, much that should be done to improve the quality of meat hygiene in this country that can be enormously beneficial to the meat consuming public, as well as to the producers, processors and purveyors of meat animals and meat products.

Quality meat inspection is costly, but the human disease and economic fraud that it can prevent when responsibly administered can make it a bargain. For example, the total cost of inspecting *all* meat and poultry produced in the United States, imported and exported, including all overhead and extraneous costs is less than \$2 per U.S. citizen per year. While the current program prevents much human disease, estimates of the costs of preventable diseases which are still acquired from meat each year exceed the annual FSIS budget.

Meat is the most costly portion of our diet. As such, it presents a constant temptation to the few unscrupulous, or merely pragmatic, industry members who would profit from the marketing of diseased animals, the adulteration or concealment of inferiority of meat products, or from policy changes that promote industrial productivity at the expense of effective inspection methods.

The Federal Meat Inspection Act of 1907 and the Poultry Products Inspection Act of 1957 (both Acts were updated in the late 1960's) mandate that the Department of Agriculture provide continuous inspections at slaughter plants examining each carcass. Such inspections are a critical point in the elimination of diseased and otherwise unwholesome meat and poultry from the food supply. For example, in 1990 these inspectors eliminated an enormous number of diseased food animals from our Nation's meat supply—over 180,000 cattle/calves, over 190,000 swine, over 20,000 sheep/goats, over 3 1/2 million turkeys/ducks and over 81 million chickens. This is of particular importance to the task of protecting consumers from foodborne disease because most of the disease agents that are particularly hazardous to humans may be carried by and transmitted through the meat of diseased food animals. The requirement, and justification for this kind of inspection is unique to food animals. A good analogy of diseased animal risk is the egg. Until a few years ago grade A uncracked eggs were known to be safe to eat raw. The only danger was from surface contamination on the shell (similar to surface contamination on a healthy beef carcass). Then, for unknown reasons, *Salmonella enteritidis* gained the ability to cross the ovary and become situated within eggs (similar to a diseased beef carcass). Thus far these eggs in the past 5 years have caused over 7,000 cases of disease and over 50 deaths in the United States. Eggs, by the way, are not under FSIS control.

Diseases of animals are not static, they have been and will be sentinels of new and/or changing patterns of disease. Furthermore, assessing disease patterns for one geographic area (as has been proposed) is reasonable only when animals are not shipped all over the United States for slaughter such as exists now. This changing of disease potential is exemplified in the past 20 years by the "new" public health risk from *Campylobacter*, *Listeria*, *Yersinia*, *Escherichia coli* 0157:H7 and *salmonella enteritidis*.

The first Critical Control Point in all Hazard Analysis Critical Control Point (HACCP) programs is always the safety of the raw food received. This is the live animal for meats and antemortem/postmortem organoleptic (sight and touch) inspection is the *only* available intervention. Indeed, this is one area where FSIS excels by assuring that no diseased animals enter the food chain. The purpose of the examination is to determine the suitability of the carcass for use as human food. The innumerable specific diseases that may affect food animals produce lesions, many of which, are identical to those produced by other diseases. A specific diagnosis is seldom possible, but an appropriate, rational disposition, based on the veterinarian's knowledge of the affect of disease processes on the animals is usually possible. Many, but not all, of the diseases which affect food animals are caused by infectious, toxic or physical agents that are hazards to human health. Traumatic injury and physiological abnormalities may, also, result in disease conditions that render an animal unfit for food.

All systemically diseased carcasses are unfit for human food. If the disease condition is limited to a part of the carcass, that part must be condemned. For this reason, a *definitive diagnosis* is not necessary to identify carcasses that may bear hazards to human health.

Traditional inspection systems are very effective in removing organoleptically detected abnormalities, but cannot be assessed for risk benefit because data is not available for determining the etiology of the abscesses, septicemia, toxemia, etc.

That causes the condemnations. The lack of data on these diseases is one of FSIS' risk assessment failures.

Organoleptic evaluation should not be ridiculed as has become a fad by the ignorant. Organoleptic evaluation is what every physician does when first evaluating a patient and only when the organoleptic findings indicate the need are further tests made.

Before we go further, let's look at how "public health persons" would/could correct all the damage that having primarily veterinarians in these programs have allowed as stated frequently this year. There is no such thing as a "silver bullet" public health expert.

There are chronic disease experts, sexually transmitted disease experts, epidemiologists, sanitarians, veterinarians, etc., who make up the "public health umbrella." Veterinarians are considered to be the only public health experts for meat/poultry (and other areas) by every country in the world in most of which they predominate even more than in the United States. Veterinarians have discovered most of these meatborne disease organisms (*Salmonella* is named after Dr. D. E. Salmon). Veterinarians have developed most of the tests for these diseases, veterinarians have defined the methods of transmission for most and most of the world's scientific literature in this area has veterinary authors. There is no other public health person who can protect the health of people rather than protect the health of pigs and to state otherwise is naive at best. The medical knowledge and abilities are present but "political" constraints have not allowed veterinarians to do what is necessary to reduce the risks in most instances following the postmortem disposition (all of which will be discussed later).

The present meat/poultry inspection laws adequately provide the legal basis for implementing better microbiological controls if the political will exists to do so with the possible exception for a broader preharvest inspection program.

What went wrong?

(NAFV has for 12 years testified to all the following before Congress numerous times and had discussions with staff numerous times; presented papers and discussions with the Secretaries of USDA, Assistant Secretaries and Administrators numerous times; participated in many symposia; was interviewed by many media and published numerous papers. All to no avail. Now *E. coli* 0157:H7 is driving a speeding train down an unknown track.)

First and foremost. The Agency has evolved into a mindset that the only skills/knowledge required of their supervisors and managers are supervisory/managerial/negotiating skills. Medical/technical knowledge is not needed. This has been stated numerous times by top management. Other philosophies that have evolved are, "it's better to be uniform than preventively correct", and "contamination of carcasses from external sources such as condensate, grease, etc. are to be prohibited but contamination from internal sources, i.e. feces, is normal and OK if not visible."

The need for current medical/technical knowledge is not recognized as pertinent to the mission since the mission has evolved into solely a "tallying of visual events." Without current knowledge and appreciation of public health impact in all levels of field operational control, there cannot be a science-based food safety program. If managers do not understand they cannot lead, motivate, evaluate, solve problems, assess changes, etc. based on current knowledge in areas of microbiology, sanitizing, food science, epidemiology, risk assessment, pathology and public health.

Inspectors with high school degrees are trained at government expense not to gain more technical knowledge that can be applied to the mission, but purely to make them eligible for promotions to higher level management positions. No degree is required. The course hours can be and are satisfied by correspondence courses. These "false" food technologists now can apply for any area or regional positions that had been medically credentialed. When they apply, they are on a separate list from the veterinarians who apply, so that the food technologists do not even compete with veterinarians. There are two job descriptions for each of these jobs and the one used is dependent on who is selected, i.e., a doctor or a "nothing." NAFV strongly supported a food technology training program requiring graduate training in meat/poultry food technology and still does.

Continuing medical/technical education has been totally absent after initial training by FSIS. (The new small refresher course at TAMU and the Ames Correlation Group are a step to help in this.) Up to now, no updating of scientific knowledge has been given, encouraged nor often even allowed.

Even in-house studies to inform your peers are discouraged or not allowed. Area/regional/national meetings when held by FSIS, contain neither scientific discussion nor new science information of any kind!

No one, for many years, has been sent for advanced training in any science area (microbiology, toxicology, epidemiology, meat/poultry science, etc.) except pathology and a very general indoctrination-type program in science.

Scientific knowledge and its application to mission objectives is ignored as a prerequisite for promotion within the *entire* inspection operations. Persons selected to chair and be members of scientific committees and task forces frequently have no scientific credentials.

None of the pilot tests for new inspection programs (515 or before) have ever attempted to evaluate their effect on disease and/or spoilage organisms.

There have been no baseline data collected on bacterial public health risk, if any, from condemned carcasses. There have been no baseline data collected on bacterial public health risks on the "passed" carcasses.

Without baselines, trends and interventions cannot be evaluated.

Sanitizing has not been evaluated. Hot water and/or chemical sanitizers have as their only purpose the killing of bacteria (disease and/or spoilage). FSIS has not tested the many significant variables under which they're used which can prevent their effectiveness nor are they even required in poultry slaughter facilities.

Numerous ways of washing or trimming feces from carcasses have been evaluated for visible effectiveness only, but little, if anything has been done to try to prevent the fecal contamination from happening in the first place.

What is FSIS doing now?

1. FSIS has slowly begun to gather baseline microbiological data on beef, downer cattle and hamburger, none of which will be statistically valid for a plant (according to FSIS). Therefore, if a new inspection program is to be tested they may not be able to compare its impact on raising or lowering risk in that plant.

2. FSIS has developed a pathogen reduction program which contains many questions seeking scientific answers and contains recommendations for development of rapid microbiological tests and preharvest evaluations of animals and agents of risk on the farms. These are needed. These are all expensive and long-term. There is little (unless it's hidden) in the pathogen reduction program that would expand the use of 30-40 year old scientific methods such as:

- a. Evaluating the cleanliness of hands, steel mesh gloves, cloth gloves, knives used to trim feces and abscesses, etc.

- b. Determining the agents responsible for the infectious disease that causes the condemnation of about 70 percent of the millions of carcasses mentioned earlier.

- c. Deciding what to do with the rapid tests if and when available since almost all (if not all) the organisms of risk get on the healthy carcasses directly or indirectly from feces which we already know. We know how they get there we just don't know the variety present. Will they allow the contamination to continue and then detect it rapidly or would it make more sense to reduce the contamination to begin with using washing of live animals, better evisceration procedures, slower lines, etc.?

- d. With preharvest inspection much valuable information can be gained, but what are realistic expectations? Thousands of more Federally employed people running around testing billions of animals? If, as many suspect, 10 percent of cattle have *E. coli* 0157:H7 are you going to condemn these approximate 10 million head and pay billions in indemnities? Or more realistically would one have a voluntary certification program that could be effective for some farms? The "great expectations" for a preharvest quick fix by many groups is comically pathetic.

- e. Better education of the consumer is needed, but the expectations here are also unrealistic. About 25 percent of the U.S. population is immunocompromised and is growing quantitatively and qualitatively. Handling raw product in the home and restaurant can be dangerous even if subsequently cooked well. Most such education programs have been amazingly unsuccessful. Much of our food is now prepared by others over whom we have no control. The turnover rate in fast food restaurants is 200 percent per year or higher. These employees are not even in place long enough to be trained well and many cannot read. Thus, we must reduce the risk for raw products of highest risk.

- f. Better medical/technical/scientific graduate training and or continuing education is desperately needed if more scientifically credible programs are to follow. Nothing is being done. Millions are spent for supervisory/managerial and union meetings everywhere. Yet, no one can go to school or attend a scientific meeting for their own knowledge. Still at the presently scheduled FSIS meetings no science is discussed only administration!

What to do?

1. Change the law to give authority for preharvest inspection to USDA/APHIS and require adequate traceback controls.

2. Fund programs to meet your risk/benefit objectives, whatever they may be.

3. Put scientifically credentialed people in charge of all science or public health programs and keep them up-to-date and promote on scientific abilities as well as managerial abilities.

4. Gather baseline microbiological data for risks on healthy carcasses.

5. Gather baseline microbiological data for risks on condemned carcasses (since they often contaminate hands, equipment and healthy carcasses).

6. Gather baseline microbiological data on whether sanitizing is really sanitizing.

7. Immediately evaluate ways to reduce fecal contamination.

8. Improve consumer education

9. With the above a more rational risk assessment can be made and preventive interventions can then be put in place.

10. Try to move to pasteurization of high risk raw product with the use of heat, irradiation, etc. Pasteurization for hamburger will be the only solution as it was for milk. Without pasteurization raw meat will never be risk free.

What about the National Performance Review recommendation?

I was one of 10 members on the NPR food safety task force. We unanimously recommended a single *independent* food safety agency, not a move to FDA.

If an independent agency is not an option, then meat and poultry remaining in USDA is the only logical cost-effect option. It makes no sense to move FSIS under the guise it would have better results in FDA when:

a. All the animal scientific expertise is in USDA, APHIS and ARS.

b. Of the latest 15-year period studied (1973–1987) of the 3,699 outbreaks where the disease had an implicated food only 23 percent were from generic products under FSIS control. Of the major foodborne disease outbreaks known in the last 10 years only one, the Washington *E. coli*, implicated FSIS controlled food, the others were all dairy, eggs and seafood involving over 30,000 cases of diseases and over 70 deaths. Why should FSIS be moved to improve it rates of about 600 cases and five deaths?

The final report of the Advisory Committee on the Food and Drug Administration, May 15, 1991 showed inadequate facilities, training and funding for foods. This report was highly concerned about the viability of the foods program and the lack of agency priority for food issues. The report also stated and I quote:

"No evidence was presented to the subcommittee to show that FDA's performance would improve if its human food responsibilities were combined with those of USDA, if it were given EPA's responsibilities or setting pesticide tolerances, or if it were empowered to regulate advertising for foods and cosmetics."

FDA has no baseline data on risks.

I reviewed a draft of the FDA Unicode for Food Sanitation in 1982, it was just published January 21, 1994.

The *E. coli* fast food chain in Washington State was in compliance with the FDA Sanitary Code though not in compliance with the State code.

With the above in mind it makes no sense to move FSIS into FDA, in fact it appears to be contraindicated.

WILLIAM J. LEHMAN

My name is William J. Lehman. I am a USDA GS-9 Food Inspector assigned to inspect meat and poultry products imported to the United States. I have been a meat and poultry inspector for more than 27 years. I am currently an Import Inspector assigned to Establishments I-47 and I-264 in Sweetgrass, Montana, a major port for meat and poultry products entering the United States from Canada. The following will update my testimony presented at last year's hearing on Food Safety and the North American Free Trade Agreement.

Last year I testified that food poisoning deaths, like the Jack-in-the-box tragedy, were certain to multiply under USDA's import inspection procedures. Since the first death in January of 1993, there have been 16 cluster outbreaks with approximately

nine (9) more deaths in over seven States. The U.S.-Canada Free Trade Agreement has reduced the protection that inspection should afford and created loopholes in inspection procedures. In the wake of the Jack-In-The-Box tragedy, the USDA pledged to overhaul the meat inspection system. I am testifying now to let you know that the problems remain.

When I started my job as an Import Inspector in October of 1987, the methods for sampling, re-inspection and disposition of imported Canadian meat and poultry products were tried, truthful and effective. On January 1, 1989, the administrator of the Import Inspection Division issued the new "streamlined" inspection procedures for Canada. Although the Canadian Streamlined Inspection Service (CSIS) is no longer in effect, FSIS' current inspection procedures continue to be inadequate to protect the American consumer. The current system boasts of "100 percent inspection" of all Canadian product, but this statement is very misleading. The system employs a method whereby approximately one out of every fifteen trucks is randomly inspected. The USDA computer selects which lots or loads are to be inspected. The other fourteen trucks are designated as "skip lots" and get a cursory inspection. Ninety percent (90 percent) of all shipments destined for import to the United States from Canada are designated as "skip lots." For "skip lots," "100 percent inspection" means inspection of paperwork only.

Beef carcasses are brought across the border in eighteen-wheel, semi-trailer trucks, each carrying approximately one-hundred and ten (110) carcasses. The trailers typically are equipped with four (4) rails, equally spaced, running down the center of the trailer. Carcasses hang, in rows of four, inside the truck. If a shipment is designated for an inspection, the carcasses are brought off the back of the Canadian truck when it arrives at the inspection facility. When the carcasses are brought out from the rear of the truck, this is called "railing out" the beef. The inspection station is built so that there is only room to "rail out" seven (7) sides of beef. This means that, at most, I can only examine the seven (7) carcasses at the rear of any truck.

In theory, I am supposed to conduct a product exam according to USDA randomly generated numbers that correspond to the load of carcasses. In practice, inspectors are verbally instructed to look only at the carcasses at the rear of a load. It is impossible to tell anything about those carcasses in the front of the trucks.

Because Canadian shippers are aware of my limitations as an inspector, it stands to reason that they will place their cleanest, most heavily trimmed carcasses at the rear of the truck in hopes that the entire shipment will pass inspection. I often see carcasses at the rear of the Canadian truck/trailer that are heavily "spot trimmed." This means that the Canadian packers are trimming off heavily contaminated areas of the carcasses in hopes that they will pass inspection. Even with an inspection system heavily tilted in favor of the Canadians, and the heavy spot trimming that I am seeing, often the meat I inspect is so dirty that I must refuse entry of the product.

I had never seen the levels of contaminated or diseased meat that I saw when CSIS was in effect. Even with the demise of the CSIS program, improvements are still badly needed. I am not alone in this belief. USDA has proposed changes to the current methods. In August of 1993, a letter was sent to all IFO Supervisors from Michael Grasso, Acting Director of the Import Inspection Division, which claimed that effective January 1, 1994, all import facilities along the Canadian border must have the capabilities to randomly inspect the carcasses as opposed to inspecting only the last seven (7) at the rear of the truck. This is exactly what should have been happening all along. A follow up letter was sent in December 1993, detailing the new inspection procedure. However, on December 27, 1993, a letter was sent which stated that the effective date for this change had been extended to January 15, 1994. On January 11, another letter was sent explaining that a working group was being formed to explore other options for carcass inspection, virtually canceling the effort to comply with the law. Therefore, the current inspection procedures that have been in effect since 1989 will remain in effect under further notice.

When I testified before Congress on February 18, 1993, I pointed out that there was no penalty for trucks that refuse to stop at the border. This is called a "by-pass." In 1989, the General Accounting Office (GAO) reported that thirty-seven (37) Canadian trucks simply refused to stop for an inspection.

On May 25, 1993, H. Russell Cross, FSIS Administrator, approved a plan to have U.S. Customs assess liquidated damages against Canadian shippers who "by-pass" inspection stations. This memo shows that from August 1992 to April 1993, there were 123 Canadian by-passes. Clearly, the by-pass problem has gotten worse in the past few years. The memo also stated that FSIS had contacted Customs about the plan and that they were willing to cooperate with FSIS in assessing liquidated damages.

On June 1, 1993, Mike Grasso sent a memo concerning the "followup on Canadian by-passes" that detailed how trucks that by-pass inspection stations will be assessed liquidated damages by U.S. Customs agents.

On July 7, 1993, I asked Mr. Kent Brimhall, U.S. Customs Port Director in Sweetgrass, about the liquidated damages provision, and he stated that he was unaware of any such provision. Mr. Brimhall had not seen any memo from USDA or FSIS on the subject, and was unaware of any agreement between USDA and Customs. Mr. Brimhall also told me that no one at the Eastport, Idaho Customs Office nor the Regional Office in Great Falls had heard anything about this new policy.

During mid-July, 1993, Mr. Mike Grasso, acting director of the FSIS Import Inspection Division, telephoned me at home. During the course of our conversation, Mr. Grasso admitted that FSIS had not yet made any attempt to reach an agreement with U.S. Customs concerning implementation of the liquidated damages policy. Effectively, there remains no penalty for trucks that "by-pass" inspection stations and proceed to place meat into the stream of commerce in the United States. Since there is no enforcement of this provision, there is no reason for Canadian shippers to stop by-passing the border inspection system.

Another concern of mine is the continuing practice of Australian meat crossing the U.S. border as Canadian meat. There is a quota limiting the amount of meat than can be imported to the United States from Australia. Under the USDA's system, Australia merely has to ship its meat through Canada where it can entirely avoid the limitations of quotas—because under the terms of the U.S.-Canada Free Trade Agreement there are no quotas applied to meat imported from Canada. At this time, Australia has already met its 1994 quota of beef it may import into the United States. However, Australia continues to ship beef into the United States through Canada to escape the quotas, strict inspection and the payment of duties owed to the taxpayers.

On February 18, 1993, Mr. Manis testified before the House Subcommittee on Commerce, Consumer Protection, and Competitiveness. Mr. Manis admitted that he had made a "mistake" in instructing me to treat Australian meat in Australian boxes entering the United States through Canada as Canadian product. On February 23, 1993, I requested this change in policy in writing from Mr. Nay. To this day I have received nothing in writing from Mr. Nay or Mr. Manis.

Since there is no written policy statement disavowing Mr. Manis' earlier instructions, I can only assume that other inspectors are continuing to treat Australian meat as if it were Canadian.

On June 2, 1993, Mr. Patrick D. Layton (ID #600114), an official representative from Ag Canada, visited Sweetgrass Inspection Station I-47 to review a refused entry of a shipment of pork legs (AGR #621275). Mr. Layton agreed with my classification of the defects. We also discussed Canadian inspection procedures for Australian/New Zealand products destined for the United States. Mr. Layton stated that there was no Canadian inspection of Australian/New Zealand product bound for the United States through Canada.

The U.S. re-inspection system relies on the documented uniqueness and equivalency of the Canadian inspection system. Since Australian product bound for the United States through Canada is not being inspected by the Canadians, the health of the American people is being put at risk when Australian meat enters the country as Canadian product.

Often, trucks that enter the inspection station at Sweetgrass are loaded with tall "combo" bins. Combo bins are large boxes made of heavy cardboard and are lined with plastic. A typical shipment of beef contains 22 combo boxes, each weighing about 2,000 pounds. The use of combo boxes reduces the costs to the packer by allowing for a greater amount of product to be shipped with less packaging material required.

The boxes are often pushed 6 to 8 feet inside the rear of the truck, and are turned in such a way that no shipping marks or labels are visible to me from the outside of the truck. It is even impossible to tell if the boxes contain meat, let alone if that meat is wholesome and fit for human consumption.

On March 30, 1993, Kathy Evans, IFO #9 supervisor, instructed me via telephone that I was not to verify shipping or labeling marks that were not visible from the outside of the rear of the truck or were difficult to see. Ms. Evans also instructed me that I could not ask other employees to verify the labels for me nor could I enter any truck or use a flashlight to see the labels. Mr. Nay also confirmed these instructions.

On April 13, 1993, Ms. Evans confirmed her instructions in writing. On April 20, 1993, I sent a "speed memo" to Secretary Espy to report on Ms. Evans and Mr. Nay's instructions. I also enclosed a photograph which clearly showed a load of approximately 40,000 pounds of Canadian beef with no visible labels, AGR number,

product name, foreign establishment number, or country of origin. Yet, per Mr. Nay's instructions, I was forced to stamp this product (and others in similar situations): "U.S. Inspected and Passed." This is not a truthful statement of the situation and it is in direct conflict with the inspection manual.

A June 25, 1993 memo from Mr. Mike Grasso, acting director of FSIS Import Inspection Division, states that as of July 19, 1993, Canadian shippers must present combo boxes at the rear of the truck in a way which will allow for label verification. The memo explains that if labels on combo bins cannot be read, one option is to "have one carton or combo bin removed or turned around for verification." Although this seems like an improvement, the memo does not explain exactly how labels will be verified and it does not say that I, as an inspector, can move a combo box, let alone enter a truck. The vagueness and limited nature of Mr. Grasso's memo, and the long history of label verification violations, suggest some areas of future difficulties.

For example, as of July 19, 1993, when trucks are packed right up to the rear door, I have been able to verify the labels on the rear boxes. When the boxes are too far up to read the labels, someone will go inside the truck and bring me a ten pound (10 lb.) box of product. I can verify the label on that one box, but I may not open it to examine the product. In addition, the memo does not detail can "have one carton or combo bin removed or turned around for verification." Additionally, if only box can be moved for verification, this does not help in verifying the remaining part of the shipment at the rear of the truck. FSIS has been slow to act on this violation of law, and Mr. Grasso's memo is sufficiently vague that I, as a meat inspector, will remain at the mercy of the Canadian shippers when verifying labels.

Clearly, with no well defined method to verify labels (other than on one carton at the rear of the truck), the integrity of the protection for the American consumer is completely undermined.

In 1970, USDA allowed for the importation of ground meat, but only in boxes that weighed three (3) pounds or less. Later in 1970, USDA clarified the regulation dealing with the importation of meat of "small size." After 1970, no meat smaller than a two inch (2") cube could be imported into the United States. Also Effectively, no one exported ground beef to the United States because it was much too expensive to do so in such small boxes.

In July, 1992, after extensive lobbying by the Australian government and a Maryland food consulting firm, Dr. H. Russell Cross instituted a change in the Federal Meat Inspection Regulations. This new regulation allows for the importation of meat in pieces smaller than two inches (2") in diameter (i.e., ground beef) at the same time eliminates the size restriction on the containers in which the ground meat can be packaged.

Now, for the first time, it is practically and economically possible for foreign meat producers to export ground beef to the United States. While technically, ground meat could be imported into the United States since 1970, in reality this was never done because of the package restrictions.

In my job as an inspector, I am now seeing very dangerous conditions as a result of the new regulations on ground meat. It is impossible for me to detect defects such as bone fragments, hair, glass, blood clots, hide, and fecal material in ground meat. In the wake of the Jack-In-The-Box tragedy, this new policy may be the most dangerous example of short-sighted management at USDA.

Because there is no way to protect the American consumer from defects in this kind of imported meat, the real health danger is that now there is nothing to stop a Canadian shipper (or one from any foreign country) from taking a shipment of meat that has been refused entry into the United States (for defects such as, blood clots, ingesta/fecal material, blood clots, bone fragments, glass, hide, and/or pathologic lesions), grinding the meat up, re-boxing it, and then reshipping it into the United States.

During my testimony before the House Subcommittee on Commerce, Consumer Protection, and Competitiveness on February 18, 1993, Chairperson Cardiss Collins showed me a U.S. Customs memo dated January 28, 1993. The memo reported that the Australians had made a substantial investment in "flaking/grinding" machines and large cardboard combo boxes and shipped them to Canada. "Flaking/grinding" machines are used to reduce large quantities of boneless, Australian meat into ground meat. This would qualify as the "minimal processing" that is necessary to then package the meat in Canadian boxes and export it to the United States as Canadian product. This practice obviously circumvents Customs regulations and quota restrictions on Australian meat imports.

The memo also reports that Canadian imports of Australian beef through November 21, 1992 (the period after the implementation of the new USDA policy allowing for the importation of ground meat) increased by twelve (12) metric tons. During

the same period, Canadian exports to the United States were up almost fifty-eight (58) metric tons.

I have testified before Congress about my fears concerning the safety of imported ground meat, and those in charge of FSIS are aware of my views, but the policy of allowing for the importation of ground meat continues.

Since Secretary Espy has announced a new policy of surprise inspections of import facilities, Mr. Niles Nay has undermined this initiative by informing me that he will warn me in advance of any "surprise" inspections. This is an unheard of policy in the history of meat inspection.

I have internally and publicly disclosed to USDA management the health and safety problems with the current inspection system. I have continued to perform my duties as instructed. Even so, my supervisors have made it clear that my disclosures are not appreciated by USDA or the industry and might damage my position within the Agency. Since the time I became a whistleblower, I have had to face hostility from my superiors at USDA and the inspection facility I-264, owned in part by a Canadian meat broker, in Sweetgrass. I am always in fear of retaliation for my whistleblowing activities. I have been the target of threats and allegations by the owners and management of inspection station I-264 on several occasions. At this time I am assigned to I-47 and have been instructed not to return to inspection station I-264 until the current allegations are resolved. The Government Accountability Project (GAP), has been assisting in my defense of these allegations and attacks. GAP is a public interest organization which provides support to whistleblowers and has been actively involved in the campaign for improved food and worker safety and I am grateful for their help.

I believe that USDA officials need to be reminded that their jobs should be motivated by a desire to protect the American consumer, not to promote "free trade." I am embarrassed to say that I have been a part of the system that has instilled confidence and that has deflated any fears or concerns on the part of consumers. The continuing deaths of children from eating USDA inspected and approved hamburgers are evidence to the fact that the present inspection system is inadequate. This practice, by the Import Inspection Division, of continually watering down inspection procedures of meat from Canada is a disgrace to American taxpayers who still think "U.S. Inspected and Passed" means just that.

I bring forward these problems with great optimism that Secretary Espy will consider them as he fulfills his promise to overhaul the meat inspection system. All I desire is for USDA and FSIS to make it possible for me to uphold my sworn duty as a meat inspector, through enforcement of all applicable laws and regulations.

DR. JOHN A. MARCY

Thank you for inviting me to comment on the progress of Federal meat inspection. I am Dr. John Marcy, food scientist with the Center of Excellence for Poultry Science at the University of Arkansas. I present this testimony on behalf of the Institute of Food Technologists (IFT). IFT is a non-profit scientific society of 27,000 food scientists, technologists, engineers and others working in related fields spanning the entire food system in industry, academia and government. IFT aims to advance public understanding of food issues by communicating substantive and timely scientific information about food science and technology.

Hazard Analysis Critical Control Point (HACCP) is a food process control management tool to evaluate possible hazards and to subsequently manage the process to prevent, reduce to an acceptable level, or eliminate those hazards from food prior to consumption. HACCP principles can and should be used throughout the food system from farm to table. It is anticipated that USDA will mandate HACCP plans from all establishments under FSIS jurisdiction. There are meat and poultry plants with HACCP plans implemented and operating now, and many foodservice operations have or are in the process of implementing HACCP principles into their operations. It is from the framework of HACCP that I will address the following:

- No amount of inspection will ensure (guarantee) food safety.
- Even with HACCP, raw products of animal origin will continue to have associated with them detectable pathogenic bacteria.
- Science and technology research will be needed to understand new hazards as they become apparent.
- Education and communication are vital components of HACCP and are needed to deal with the hazards we know today, and the hazards we will face in the future.

No amount of inspection will ensure (guarantee) food safety

We have focused on a perceived failure of the inspection process, but the failure is only in the perspective of an impossible mission and unrealistic expectations. *No inspection or finished product testing program can guarantee food safety!* At best, both will only give us snapshots and indications if something is fine or not. That was the driving force behind the origination of the Hazard Analysis Critical Control Point concept. That was real 20 + years ago and the reality remains the same. On the other hand, the meat and poultry industries have changed dramatically in 20 years . . . and so has inspection. One of the major strengths of HACCP management is the flexibility to meet new conditions. Practiced correctly, the company will challenge the current HACCP plan on a routine basis to look for weakness; to continuously look for ways to improve or to address new knowledge. This is where inspection programs and science fit together to work with a company operating with a HACCP food safety management system. Inspection programs are needed to verify the process, to audit the system, and to be a vigilant reminder of the company's obligation and responsibility to provide safe products. Science provides new understanding of the organisms that HACCP is meant to control and possibly new ways by which to control these organisms.

Even with HACCP, raw products of animal origin will continue to have associated with them detectable pathogenic bacteria.

The *Pathogen Reduction Program* states that USDA intends to deal with all serious pathogens through detection and eradication. If USDA is referring to eradication of the bacteria at the farm level, then the goal is not logical. The eradication or extinction of a bacterial species from nature would be impossible to achieve or to verify. *Farm animals are a part of nature and cannot be totally isolated from the rest of nature!*

The HACCP systems monitor and control the processes that will prevent, reduce to acceptable levels, or eliminate these hazards. Because some pathogens are more dangerous than others, there is not an acceptable level for some organisms, such as *Salmonella* and *E. coli* O157:H7, while there may be an acceptable level for an organism such as *Staphylococcus aureus* that requires large numbers to produce toxin and does not compete well on raw meat. Therefore HACCP dictates that prevention or elimination of these dangerous bacteria must occur through an appropriate process before consumption. No operation in the present slaughter process has been demonstrated to either totally prevent or eliminate pathogenic bacteria. Therefore it can be expected that even with the best HACCP plan in a USDA facility that distributes raw meat or poultry, there will continue to be pathogenic bacteria associated with raw product. An operation that is not part of the present process that can eliminate these organisms is irradiation. IFT would encourage the approval of irradiation for products in addition to poultry so that the choice to purchase **safer** meat and poultry can be made in the market place.

Science and technology research will be needed to understand both current and new hazards.

Just like the first E. coli O157:H7 outbreak in 1982, new hazards are only identified after several incidents involving illness, injury, or death have occurred to document that there is, in fact, a new hazard.

FSIS has proposed extensive study of the on-farm characteristics of bacteria pathogenic to humans. This study be conducted because the knowledge would be extremely important to the research and possible development of efficient reduction/control strategies, such as competitive exclusion. These bacterial species and their many strains are either ubiquitous or not enough is known about their reservoirs to even begin to understand control in domestic and/or wild animal populations. We can probably learn something from the husbandry practices of countries like Denmark and Sweden, bearing in mind that their annual production is only a tiny fraction of the United States.

To detect these organisms, FSIS is now funding research in hopes of

To detect these organisms, FSIS is now funding research in hopes of development of very rapid, inexpensive, specific, and simple tests that will indicate the presence of microbes pathogenic to humans. The knowledge gained by the research necessary to the developments of such methods may well prove beneficial to society in ways not imagined similar to the benefits that society has reaped as a result of the space program. However, the ability to detect human pathogens associated with live animals or raw meat does not solve how we deal with their presence. The organisms

in question today do constitute a hazard, but it is how we deal with that hazard that will make a difference.

Education and communication are vital components of HACCP and are needed to deal with the hazards we know today, and the hazards we will face in the future.

If we (society) prevent animals or meat from entering the food supply simply because of the presence of bacteria, then we are not managing our food supply properly. We know how to produce food . . . we feed ourselves and a large part of the world. But everyone knows how to handle food, individuals do make mistakes, and foodborne illness does occur even though it is preventable.

Two sections of the FSIS plan targets information and education to the foodservice industry and consumers. Since almost 80 percent of supermarkets offer hot foods to the consumer, it is imperative that that segment of the retail industry be included in any food safety education initiative. Most importantly, education needs to be targeted at that critical point where the most frequent and serious food handling errors can occur: the foodservice/retail food operation and the consumer's home.

In a recent issue (January, 1994) of Nation's Restaurant News commemorating the 75th anniversary of the National Restaurant Association, Dr. William P. Fisher, executive vice president of the National Restaurant Association, listed 10 goals for the foodservice industry of the year 2000. One of those goals was:

"All foodservice units will be utilizing the SERVSAFE Applied Foodservice Sanitation program produced by the Educational Foundation of the National Restaurant Association, along with the many other educational materials offered, to confirm and continually reinforce with consumers the safety of food produced and the professionalism of persons working in our industry."

Shortly after the *E. coli* outbreak, the Educational Foundation formed an Industry Council on Food Safety. The Council is a coalition of independent and chain operators and industry associations who have demonstrated their commitment to food safety by agreeing to maintain a SERVSAFE-trained manager in every unit at all times. To date, over 125 chain CEOs have joined the Council. This commitment is in addition to the 375,000 persons already trained and certified by the Educational Foundation.

Despite the seemingly large number trained, the goal of both industry and regulatory agencies that all managers be trained will require the resources and commitment of all stakeholders in an improved safety system. The foodservice industry employs almost 9 million people in more than 730,000 units. At two to three supervisory personnel per unit, one can estimate a training challenge of from 2 to 3 million persons or more.

FSIS proposed a joint HHS/USDA initiative to educate all restaurant managers and staff. That is a commendable goal that should have a very high priority and support, especially if it includes the foodservice industry as a partner. This education is necessary for HACCP to work at the real critical control points; the time/temperature relationships of cooking, holding, cooling, and reheating. The inclusion of a food safety knowledge requirement in FDA's recently published model code, development of a model certification program by the Conference for Food Protection, and an increase of mandatory training requirements by State and local health officials, would make the timing for the endeavor now.

DAVID L. CARNEY

I would like to thank the subcommittee for the opportunity to represent the concerns of the approximately 6,560 Food Inspectors that attempt to enforce the meat and poultry inspection laws and regulations that are promulgated by the U.S. Department of Agriculture, Food Safety and Inspection Service.

The issues that the subcommittee has asked for comment on, are very significant in relation to a comprehensive inspection program and the production of clean, wholesome, unadulterated and properly labeled products. The National Joint Council that represents the Food Inspectors are often criticized as using food safety issues as a union tactic, however, to the contrary, we represent the last line of defense between the narrow minded bureaucracy at the Department of Agriculture, a profit motivated industry and the consuming public.

The previous hearing that this committee held was to review the Federal meat inspection programs and the regulation of coliform bacteria. This hearing resulted in the culmination of 12 years attempted deregulation and the involvement of a pro-industry administration.

With all of the attention focused on food safety by the *E. coli* outbreak, I will gladly respond to the attempted progress of food inspection related to public health:

a. At this time, a Clean Meat Production Emphasis (CMPE) program has been initiated for:

- (1) Removal of ingesta, fecal and milk contamination from meat carcasses,
- (2) Boneless meat reinspection and removal of ingesta and fecal contamination from fresh meat products and,
- (3) Beef carcass acceptable quality levels . . . for domestically slaughtered and inspected beef carcasses and related red meat species.

This is nothing more than a specific emphasis to the existing Meat and Poultry Inspection Regulations and FSIS Directives.

Also, the U.S. Department of Agriculture is negligent in addressing fecal and extra-neous contamination related to poultry production.

b. To further augment CMPE, there has NOT been standards for disease causing microorganisms nor the development of rapid bacterial tests.

c. The U.S. Department of Agriculture continues to erode consumer protection by permitting food to be produced at wholesale clubs, retail exempt establishments and "less-than-equal-to" State inspection programs. The continuous declining Federal budget makes this a dangerous alternative to the inspection process.

d. The Pathogen Reduction Program appears to have met an obstacle . . . in the form of the industry, to which it is directed. The obstacle is based on interpretation of pathogens and industry responsibility along with the contradictory involvement of FSIS management.

e. Hazard Analysis Critical Control Point (HACCP) has become an attempted regulatory extension to industry. HACCP met a controversial demise when it was designed to be a cumbersome regulatory inspection extension. HACCP was essentially designed to be an industry quality control process, NOT a regulatory inspection program.

f. Focus of food-borne illness needs to be expanded outside of the slaughtering and processing of regulatory inspected products. In a recent publication the table of food-borne related illnesses are:

Restaurant and Food Preparation 77 percent
Home related 20 percent
Regulatory Inspected 3 percent

This indicates a need for further regulation of the "food preparatory industry" and consumer education.

g. Risk Assessment for food inspection has been approached as a systematic attempt to recognize and know contaminants in meat and poultry slaughter and processing. The theory of Risk Analysis evolves around contaminants that pose a threat to public health causing a certain portion of the public to be expendable. FSIS is attempting to develop an inspection program with a list of known contaminants and the lethal doses as a "bench mark" for consumer safety. This is not in any way what the consumers of meat and poultry products deserve.

The basic organoleptic inspection system that is presently in place, provides a foundation for an adequate inspection program that was designed by the enactment of The Federal Meat Inspection Act and The Poultry Product Inspection Act. This can significantly be enhanced with a more scientifically based inspection program with the necessary tools and education. There is no reason that this can be accomplished in a relatively short timeframe.

It has been a previous recommendation of the National Joint Council, that to develop an optimal regulatory food safety system would be to maintain the Food Safety and Inspection Service in its' present form, however, it should become an autonomous agency to continue meat and poultry inspection based on scientific principles. We would further recommend that FSIS be removed from the authority of USDA Marketing and Inspection, with direct reporting to the Secretary of Agriculture from a self-governing body, comprised of management, supervision and the labor/inspection force.

Development of inspection principles and regulatory programs would be done through consensus building from the FSIS self governing body, consumer constituents, industry and scientific academia.

To conclude, the National Joint Council of Food Inspection Locals would like to thank the subcommittee for the opportunity to submit our comments and we enthusiastic look forward to working with this committee to develop a more scientific addendum to our present organoleptic inspection foundation.

DR. PAUL BLAKE

I am Paul Blake, M.D., Division of Bacterial and Mycotic Diseases, National Center for Infectious Diseases, Centers for Disease Control and Prevention (CDC). I am pleased to respond to the subcommittee's invitation to provide testimony on infections caused by *Escherichia coli* 0157:H7 (*E. coli* 0157:H7). This testimony will primarily address information regarding the bacterium *E. coli* 0157:H7 since testimony presented to this committee on February 5, 1993.

E. coli 0157:H7 is an emerging cause of foodborne disease. CDC first determined that it caused illness in people in 1982. Subsequent investigations by CDC have shown that infection with *E. coli* 0157:H7 may result in mild diarrhea, severe bloody diarrhea, hemolytic uremic syndrome, kidney failure, and death.

No outbreaks of *E. coli* 0157:H7 are known to have occurred anywhere in the world before 1982. During the 11 years between 1982 and 1992, we know that at least 25 such outbreaks occurred in the United States. In 1993, we are aware of 17 clusters of *E. coli* 0157:H7 infections in 12 States; however, some of these clusters may actually be unrelated cases that occurred over a short period rather than outbreaks. As clinical laboratories in more areas begin to culture stools for *E. coli* 0157:H7, more clusters are being recognized.

Although outbreaks such as the recent outbreak of more than 600 cases of bloody diarrhea in Washington and other Western States gain attention because of their catastrophic results, cases associated with such outbreaks include only a small portion of the actual number of cases of *E. coli* 0157:H7 infections in the United States; in reality, there are many more cases of *E. coli* 0157:H7 infections that are not linked to known outbreaks. During 1985 and 1986 a study conducted in a health maintenance organization (HMO) in the Puget Sound area of Washington State showed that laboratory-confirmed *E. coli* 0157:H7 infection occurred in 8 of every 100,000 persons in the HMO. If we apply this infection rate to the entire country, we obtain an estimate of over 10,000 cases of *E. coli* 0157:H7 infections each year in the United States. This would be a very low estimate of the actual disease rate because it does not count ill people who did not seek medical attention, or those who saw a doctor but did not have a confirmatory stool culture for *E. coli* 0157:H7. Although most documented infections have occurred in Northern States, infections have been observed in all regions of the country.

Our investigations have shown that *E. coli* 0157:H7 infections can be spread in several ways. The organism is highly infectious and can spread from spread from person to person in child care facilities and within families. It can be spread by contaminated drinking water and even by swimming in contaminated water. Various foods and beverages have caused illness, including ranch dressing, mayonnaise, apple cider, roast beef, yogurt, and unpasteurized milk. However, most cases are apparently caused by eating insufficiently cooked ground beef.

The outbreak of *E. coli* 0157:H7 illness in the Western States last year was the largest ever reported. The outbreak was detected in mid-January of 1993 when children with *hemorrhagic colitis* and *hemolytic uremic syndrome* were admitted to a Seattle hospital. A few days after learning about ill persons, a team of local and State health authorities, including a CDC epidemiologist assigned to the Washington State Department of Health, implicated hamburgers served by a fast food restaurant chain as the source of infection. Ultimately, CDC sent five teams with 13 medical and veterinary epidemiologists to investigate the outbreak. The CDC investigators worked with State and local public health officials in all instances. Many more epidemiologists and microbiologists at CDC in Atlanta supervised and supported the investigations, analyzed strains of *E. coli* 0157:H7, and informed the public by frequent communications with the news media and through communications with State and local health officials.

Over 600 people became infected, 4 died, and 56 developed a serious complication, hemolytic uremic syndrome. Information from the investigations was shared with local, State, and Federal agencies. These investigations traced infections to eating hamburger. They led to 1) rapid recall of the contaminated hamburger, limiting the

size of the outbreak; 2) new cooking requirements for hamburgers; and 3) identification of factors that facilitate person-to-person spread of infection in child care centers.

Our experience with *E. coli* 0157:H7 illustrates important lessons. As documented in the Institute of Medicine (IOM) report on emerging infections and microbial threats to health, we can eject new infectious diseases to continue to emerge and spread in the United States as a result of microbial evolution and technological change. Many conditions with an unknown cause, such as hemolytic uremic syndrome, can turn out to be foodborne. The link to a specific mode of transmission is not always initially obvious, and a broad range of expertise is sometimes necessary at the beginning of an investigation to determine whether the disease in question is foodborne or is spread by some other route. The earlier outbreaks of *E. coli* 0157:H7 infections and the current problem highlight the need for rapid epidemiologic assessment of new or unusual diseases and for a well-functioning network of State and national public health agencies and laboratories, as recommended in the IOM report, to detect the emergence of pathogens such as *E. coli* 0157:H7. Prevention also requires close multiagency collaboration, especially for organisms with potentially devastating consequences and the ability to spread rapidly.

CDC has continued its decade-long efforts to combat *E. coli* 0157:H7 infections by improving surveillance, responsiveness, and prevention activities. To improve surveillance, CDC has done the following:

- Presented the problem posed by *E. coli* 0157:H7 infections in the United States to the Council of State and Territorial Epidemiologists (CSTE), which passed a resolution recommending that *E. coli* infections be made reportable by the States. When CDC presented testimony to this committee in February 1993, *E. coli* 0157:H7 was reportable in only 10 States. At present, infection by this organism is reportable in 17 States and is in the process of becoming reportable in an additional 20. We are working with CSTE on a standardized surveillance case definition to facilitate data analysis.
- Completed a 2-year multicenter study of *E. coli* 0157:H7 infections, which showed that the organism is more common than any other pathogen in persons with bloody diarrhea. This highlights how critical it is for clinical laboratories to culture diarrhea stools, especially those that are bloody, for *E. coli* 0157:H7, and to report the results to public health authorities.
- Presented an update on the epidemiologic, clinical, and microbiologic aspects of *E. coli* 0157:H7 infections to the 1993 annual meeting of the American Society for Microbiology. These presentations stimulated great interest, so many additional clinical laboratories are now culturing diarrhea stools for this pathogen and reporting isolates of *E. coli* 0157:H7 to their State health department.
- Presented the latest information and heightened clinicians awareness about *E. coli* 0157:H7 infections to infectious disease physicians at the 1993 annual meeting of Interscience Conference on Antimicrobial Agents and Chemotherapy (ICAAC).
- Succeeded in having a special code assigned to hemolytic uremic syndrome in the next edition of the International Classification of Diseases (ICD), the codes used to classify diseases in humans. This should help assess the frequency of hemolytic uremic syndrome in the United States.
- Began surveillance for clusters of *E. coli* 0157:H7 infections in the United States. In 1993, 16 such clusters had been identified in 12 States.

To improve responsiveness to the challenge of *E. coli* 0157:H7 infections, CDC has done the following:

- Developed a rapid subtyping method for *E. coli* 0157:H7 strains, which permits investigators of outbreaks to distinguish strains that are part of the outbreak from those that come from other sources, so the source of the outbreak can be identified.
- Began planning with State epidemiologists, USDA, and FDA for a coordinated response to *E. coli* 0157:H7 outbreaks; this system will be similar to the system currently in place for outbreaks of *Salmonella* serotype Enteritidis infections.
- Trained approximately 120 epidemiologists in the basics of outbreak investigation, including investigation of foodborne outbreaks caused by *E. coli* 0157:H7. Continued to serve as the national reference center for *E. coli* 0157:H7 infections, giving advice and assistance to public health officials and others all over the country.

To improve prevention activities, CDC has done the following:

- Completed a 2-year multicenter case-control investigation of sources of sporadic *E. coli* 0157:H7 infections. Most of the illnesses were associated with eating undercooked hamburger.

- Produced a pamphlet on *E. coli* 0157:H7 infections for public education which, with your consent, I will submit to the record.¹³
- Engaged in an active speaking campaign before medical, regulatory, producer, food industry, and consumer audiences.
- Consulted closely with the Animal and Plant Health Inspection Service at USDA to help them plan ecologic studies of the spread of *E. coli* 0157:H7 within cattle herds.
- Began planning to survey the prevalence in the United States of the practice of eating undercooked hamburger, just as CDC determines the prevalence of other behavioral risk factors for diseases that are not foodborne.

Despite this progress, many questions about the epidemiology of *E. coli* 0157:H7 remain. In addition to better surveillance, control and prevention of *E. coli* 0157:H7 infections will require a greater understanding of the environmental ecology of the organism, efforts to control contamination of food products at the source and during slaughter and processing, and education of consumers and the food service industry on the hazards of raw or undercooked foods and on proper cooking and preparation techniques. This will require continuing collaborative efforts of CDC with local and State health departments, USDA, FDA, universities, and all aspects of the food industry. We have identified four activities that will lead to better control of foodborne disease. These activities are dependent upon adequate resources at the Federal, State, and local levels.

STRENGTHEN SURVEILLANCE FOR EMERGING HUMAN PATHOGENS

Effective public health surveillance of foodborne disease at the Federal, State, and local levels, including increased laboratory capacity, is key to developing, implementing, and evaluating prevention and control policies. As emphasized in the IOM report, strengthened surveillance capacity is critical to the recognition and control of infectious diseases. CDC is developing electronic systems that will make it easier and faster for State health departments to report recognized and emerging foodborne pathogens to CDC.

RAPID AND EFFECTIVE REACTION TO FOODBORNE DISEASE

With rapid electronic reporting of foodborne pathogens by States, CDC can analyze the data immediately and take appropriate action in cooperation with the States, FDA, and USDA. CDC has developed a computer-based data management and reporting system, the Public Health Laboratory Information System, and is developing software modules for recording the incidence of foodborne pathogens. CDC is assisting States in installing this system in all public health laboratories. Another increasingly important element in foodborne disease control is rapidly transporting pathogens to CDC for detailed subtyping, which can often help distinguish outbreak-related strains from other strains.

Another critical issue for rapid and effective response to foodborne disease is maintaining and strengthening CDC's capacity to investigate foodborne disease outbreaks. Outbreaks are a clear indication that something important has gone wrong. Investigation of such events is our primary tool for determining how similar episodes can be prevented in the future. Through outbreak investigations, CDC identifies new pathogens, new foods transmitting these pathogens, and the problems in production, processing, cooking, or handling that cause outbreaks. Results of carefully conducted outbreak investigations also can open dialogue with food producers, identify problems requiring further research, and provide the impetus and justification for regulatory change.

CLOSER COORDINATION AMONG RISK MANAGEMENT AGENCIES

CDC works closely with State health departments and with FDA and USDA to control foodborne disease. CDC and FDA have a long history of collaborative activities, including those that form the basis for our experience with active surveillance for foodborne disease. The USDA's Animal and Plant Health Inspection Service (APHIS) has assigned a veterinary epidemiologist to CDC; this has enhanced our ability to track foodborne disease problems back to problems in livestock and poultry production. USDA's Food Safety and Inspection Service (FSIS) recently assigned a veterinarian to CDC, which should enhance our ability to investigate the slaughter and processing environment.

¹³ Pamphlet is retained in Committee files.

PROACTIVE FOODBORNE DISEASE PREVENTION PROGRAMS

Modern efforts to control foodborne disease are going beyond simply inspecting the final food product, which can not detect every hazardous food item. Increasingly, the emphasis is on risk-based inspection. We must identify the critical points in the food production chain where problems can occur and focus attention on those critical control points to ensure a safe final product. CDC's foodborne disease activities help identify these critical control points.

The ultimate measure of success of risk-based inspection systems will be their impact on foodborne illnesses in humans. More completely identifying foodborne hazards, characterizing their risk, and setting foodborne disease prevention priorities will require enhancing the current surveillance systems and instituting long-term active surveillance. The planned informational labels for meat and poultry are an excellent step in the direction of educating food workers and consumers about the risk associated with raw foods, and adequate surveillance will permit evaluation of the effectiveness of that program.

An effective public response will require development of a sentinel surveillance system, in which we would help a small number of sites around the country conduct active population-based surveillance of sporadic cases as well as of outbreak-related cases. By improving the laboratories and providing for investigation of a sample of sporadic cases, we would be able to estimate the proportion of cases attributable to specific pathogens and foods, and we could then extrapolate those data to the national population to arrive at better estimates of the national foodborne disease problem. Furthermore, we would be better able to evaluate the effectiveness of food safety programs and the impact of regulatory change.

In summary, CDC's integral role in foodborne disease prevention is complementary to those of FDA, USDA, and State and local authorities. Meeting emerging foodborne disease problems in the 21st century will require enhanced programs to determine 1) who is at highest risk for foodborne infections and severe outcomes, 2) what are the important causes of foodborne diseases, 3) what are the newly emerging foodborne disease threats, 4) what are the products, processes, and practices that contribute to foodborne infections, 5) what are the effective prevention and control strategies which will minimize contamination of food by disease-producing microorganisms, and 6) how effectively are such strategies implemented.

Thank you for the opportunity to present this testimony to the committee.

CONSUMER FEDERATION OF AMERICA

INTRODUCTION

We wish to thank the Chairman, Senator Thomas A. Daschle and the committee for inviting the Consumer Federation of America to submit a statement for the record in connection with the hearing on Federal meat inspection activities 1 year after the Washington State outbreak of illness caused by *E. coli* O157:H7 bacteria in ground beef. You asked Consumer Federation of America (CFA) to comment on what changes in the meat inspection system have been implemented, the effectiveness of these changes, and what still needs to be done to provide consumers with a safe meat supply.

CFA is a national consumer advocacy organization, representing over 240 State, local and national organizations with a combined membership of more than 50 million consumers. For many years CFA and its constituents have pressed for major reform of meat and poultry inspection to protect the consumer from dangerous foodborne illnesses. The 1993 Consumer Assembly resolutions on food safety include the following:

CFA insists on adequate enforcement of safety standards including but not limited to standards for food additives, naturally occurring contaminants, animal drug residues, pesticide residues, and pathogenic microorganisms. . . . CFA supports new standards where necessary to strengthen Food and Drug Administration and United States Department of Agriculture enforcement, inspection powers, and budgets. We oppose shifting Federal responsibility for inspection to private industry (emphasis added).

Early in 1993, national attention was drawn to the West Coast outbreak of *E. coli* O157:H7 traced to contaminated and insufficiently cooked ground beef. That outbreak caused over 500 illnesses, claimed the lives of four children and cost millions

of dollars in medical care. However, this was only the most recent and dramatic example of a long term public health problem. Since 1985, three reports from the National Academy of Sciences have faulted the present meat inspection system which still relies on inspection by feel, touch and smell. The most serious public health threats to the Nation's food supply are caused by bacteria, virus and chemicals—none of which can be detected by these methods. Microbiological contamination, which is estimated to cause at least 6.5 million illnesses and 9,000 deaths per year, can only be discovered by scientific tests.

MEAT INSPECTION REFORM: THE ACCOMPLISHMENTS AND REMAINING AGENDA

At last year's hearing, Secretary of Agriculture Espy promised Congress to develop a safe handling label for raw meat and poultry, issue a standard of zero tolerance for fecal contamination of beef and poultry, institute a system which would allow USDA to track a package of contaminated meat through its handling at each point from farm to store and, most important, to overhaul the meat inspection program.

The Safe Handling Label: Consumer and public health activists have been asking for such a label for over 20 years. We are pleased that a safe handling label, which explains to the consumer why thorough cooking and safe handling is essential for all raw meat and poultry has been proposed by USDA, and should become mandatory in 1994.

Fecal Contamination of Meat and Poultry: A year ago the Secretary pledged to institute a zero tolerance for fecal contamination of meat and poultry because feces, milk and ingesta harbor dangerous bacteria that cause foodborne illnesses such as Hemolytic Uremic Syndrome, salmonellosis and *campylobacteriosis*.

CFA is pleased that the Department has instituted and issued guidelines for enforcing a policy that inspectors not approve beef carcasses contaminated with feces. However, the policy has not yet been extended to poultry. Poultry carcasses also are frequently contaminated with feces—USDA studies indicate that one-third of broiler carcasses are contaminated with pathogenic bacteria. Hosing off the visible contamination does not guarantee that microscopic bacteria and virus have been removed—in fact some studies have shown that cleaning fecal contaminated meat with high powered hoses may actually imbed dangerous bacteria into the meat.

A System to Trace Meat and Poultry Back to its Origin: In order to (1) take effective steps to contain an outbreak of foodborne illness and (2) make the meat inspection system more effective, USDA must be able to stop contamination at its source. A year ago Secretary Espy said that USDA could do more right away to require slaughterhouses to keep better records and enable contaminated meat to be traceable to its source. However, USDA has not yet sent proposed legislation to the Hill which it has said it needs in order to have the authority for mandatory animal traceback.

Overhaul the Meat Inspection System: Since 1985 the National Academy of Sciences has stressed the need for a science-based meat and poultry inspection system and CFA agrees that the establishment of a modern meat and poultry inspection system is long overdue. The USDA should take immediate steps to improve inspection, testing and sanitary processes to reduce the disease-causing microbial contamination of all meat and poultry. It is essential that such a reformed inspection system include rapid scientific tests for microbial contamination.

Secretary Espy has indicated that a rapid test for a gross bacterial mode may be available soon. However, the Federal Safety and Inspection Service (FSIS) still has no organized program to develop rapid tests to detect the range and quantity of pathogenic organisms that contaminate raw meat and poultry. Furthermore, the Agency has established no goals or timetables for completing development and putting the tests to work in meat and poultry processing plants.

HAZARD ANALYSIS AND CRITICAL CONTROL POINT SYSTEM (HACCP)

We understand that USDA wants to establish meat and poultry processor HACCP systems as a major element of the Department's effort to increase the safety of meat and poultry. It needs to be made clear, however, that HACCP is not primarily a health and safety regulatory program. It is a process or quality control system which a company can apply to virtually any type of manufacturing. It can be designed to improve the appearance, taste, shelf life or safety of their products. An effective food safety HACCP system must be designed to: (1) identify levels of bacterial contamination (2) check for that contamination at critical control points, and

then (3) prevent the future contamination at those points. For example, if the prevention of foodborne illness is to be effectively targeted by a HACCP program, USDA must first gather scientific data to learn how much of the particular organisms are needed to make someone ill and also at what point(s) in the processing these organisms contaminate the product. Only then can one build into the HACCP meaningful standards of safety and know what are the critical control points for attention.

If a Federally mandated HACCP is proposed with the purpose of significantly increasing the safety of meat and poultry, USDA must have important regulatory authority and assure the public that the food safety elements of HACCP are scientifically based.

Meat and Poultry HACCP Systems must:

- Demonstrate that the application of the USDA HACCP program will result in cleaner, safer food that is less likely to cause foodborne illness.
- Develop guidelines for acceptable levels of bacterial contamination. This involves developing scientifically based maximum dose levels for particular pathogens.
- Develop data to demonstrate that any visual and physical tests applied in monitoring and verification are accurate and adequate to improve food safety.
- Make available to the public all plant HACCP plans and records relating to Federal inspector action to enforce safety in HACCP plants.
- Undertake a full public examination—which includes the significant participation of public health experts—of all issues before HACCP regulations are published. (CFA is pleased that USDA has proposed a Roundtable discussion for this purpose.)

Adequate Legal and Regulatory Framework for a New Inspection System: It seems certain that the implementation of HACCP will lead USDA to propose ending the traditional "continuous inspection" that has characterized meat and poultry inspection. The present system has an insufficient scientific base, but the presence of inspectors in the plant provides some assurance that basic sanitation standards are usually met. These standards reduce the possibility of *extreme* bacterial contamination and foodborne illness. Therefore, CFA believes that any HACCP program must, at a minimum, include:

- Federal unannounced, random inspections with frequency based on risk associated with the product and operation as well as on the compliance history of the plant.
- Independent certification hazard analysis experts and plant personnel conducting HACCP procedures.
- Public access to all plant records related to critical control points, verifications, deviations and corrections.
- Monthly publication of names of plants that violate HACCP requirements.
- Authority to impose civil penalties on companies that violate inspection regulations or laws.
- Whistleblower protection for plant employees. If plant employees replace Federal inspectors in providing public health protection, the law must protect them against losing their jobs if they report public health hazards.

CONCLUSION

The bottom line for consumers is that USDA must remain responsible for the stamp on every package of meat and poultry which states that it has been "Inspected for Wholesomeness and Passed by the U.S. Department of Agriculture." Federal responsibility for meat and poultry inspection should not be shifted to private industry. The American consumer has a right to expect high public health standards from whatever combination of mandated HACCP system (based on USDA established scientific standards) and Federal Meat Inspection Program is employed to ensure the safety of meat and poultry.

SAFE TABLES OUR PRIORITY (STOP!)

It is only fitting that we, as a Nation, mark the first anniversary of the Jack-In-The-Box outbreak by determining how effectively we have responded to this tragedy. This Pacific Northwest epidemic was the 21st recorded *E. coli* outbreak since 1982. It's time to make long overdue corrective measures become policy. This horrific lesson in food safety should never be repeated. *But, . . .*

Less than 3 weeks ago, Michael and Diana Nole marked the anniversary of the the torturous death of their only child—2-year-old Michael Nole, the first Seattle victim to die in the Jack-In-The-Box outbreak. Less than 3 weeks ago in Seattle, Gaylon and Holly Scott buried their only child, Kevin, from *E. coli* 0157:H7.

How morbidly ironic that the Noles had to observe the dreaded anniversary of their own son's death consoling another grief-stricken family in their own home town. Kevin Scott, the only child his parents can have, fought a heroic battle for life, but his little body was no match for this virulent pathogen. He died on January 23, 1994, one of the more recent casualties in the deadly *E. coli* wars. This somber anniversary is cause for alarm as 1 year later grim statistics tell us *E. coli*'s death toll continues unabated. How tragic that the systems responsible for this onslaught remain unchanged.

Kevin's death, on the anniversary of the outbreak, screams out for action. We can no longer endure more meetings, press conferences, and rhetoric from the USDA. This agency must live up to the trust the American people once placed in this supposed guardian of our safety.

Little Kevin's death didn't make national news, (reports of *E. coli* 0157:H7 are too commonplace to make the papers), but he should be very important to this committee. His death, one of the latest in a year of *E. coli* carnage, delivers a compelling message—the United States consumer has been betrayed by a government agency whose very name, Food Safe and Inspection Service, proclaims the job we can no longer trust it to do.

Are there measures in place to prevent a tragedy like the Northwest outbreak from happening again? Unfortunately, the evidence speaks for itself—NO.

The USDA's major response to the Nation's largest *E. coli* outbreak has been to focus attention on consumer responsibility and search for reasons cattle become carriers of this bacterium. What their researchers neglect to pursue is why this bacteria not remain safely contained in the cow's intestines. It hosts meeting after meeting talking about the problem from "farm to table" and dances around the issue of fecal spreading slaughterhouses. There has been no fundamental change at the slaughterhouse—the source of *E. coli* contamination. Damaged lives all across this country attest to this lack of corrective action.

We would ask this committee to carefully consider the following information:

In the 12 months/following the Jack-In-The-Box outbreak, more recorded *E. coli* 0157:H7 deaths have occurred in at least:¹⁴

- California
- Maine
- Illinois
- Indiana
- Michigan
- Texas
- Washington

Since the Jack-In-The-Box tragedy, the Center for Disease Control in Atlanta has recorded 16 outbreak/clusters of *E. coli* 0157:H7. Health departments, newspapers, and victims report clusters in the following States:¹⁵

- Alabama
- California
- Connecticut
- Illinois
- North Carolina
- New Mexico
- Montana
- Maine
- Massachusetts

¹⁴ CDC statistics, newspaper reports, victims information.

¹⁵ Ibid.

States—Continued:

Oregon—4 separate outbreaks
 Pennsylvania
 Washington—8 outbreaks
 Texas

Will it happen again? The question is not will it happen, but where. Unless changes are made immediately this fecal pathogen will kill again, and again.

While large outbreaks garner the Nations' attention, sporadic cases like Kevin Scott's sound an alarm government cannot ignore the Centers for Disease Control in Atlanta warn that one sporadic case of HUS (the serious disease complication of *E. coli* 0157:H7 infection) can be a "sentinel event" indicating another unrecognized outbreak.¹⁶

Outbreaks are usually detected because of multiple cases of Hemolytic Uremic Syndrome (HUS). This once obscure disease has increased in the last decade, becoming the leading cause of renal failure in American children. HUS strikes 7,500 victims annually and the CDC cautions that as many as 95 percent of HUS cases are *E. coli* 0157:H7 induced. To extrapolate from these figures, there may be as many as thousands of unrecognized outbreaks of *E. coli* poisoning per year.

Many outbreaks have gone unrecognized because mechanisms have not been in place to detect them. (See attached epidemiological chart¹⁷.) Now that over 30 States have *E. coli* reporting laws (a tenfold increase over previous years), the statistics are beginning to accumulate. Victims and the public will be raising even louder cries for accountability and sweeping change. Science is catching up, surveillance is improving, and victims are booming informed.

The deregulation of the meat industry corresponds directly to the timing of a dramatic increase in *E. coli* outbreaks and HUS cases. Deregulation brought about increased line speeds, corporate self-inspection programs, and cutbacks in the size and power of the Federal meat inspection force. These changes have all been implicated in the increasing *E. coli* 0157:H7 contamination of our food supply.

The impact of this one pathogen, reported to be present in 1–4 percent of retail samples of America's red meat, is devastating. Consider the following statistics, provided by the USDA, on the toll the *E. coli* 0157:H7 bacteria exacts from the American consumer:¹⁸

389 deaths per year
 20,488 cases of infection per year
 \$610 million in medical and productivity costs per year.

The staggering annual medical and productivity cost of this one pathogen equal the budget of the entire meat inspection system of the United States.

Changes Attempted over the Last Year

Zero Tolerance

The important zero tolerance initiative is a welcome move toward change. Although it was undermined within days of its announcement by F. 5.1.5. management (the infamous memo by a Cargill lobbyist on his meeting with Dr. Cross),¹⁹ and the initial draft offensively allowed ¼" fecal matter exemptions²⁰ this initiative is a step in the right direction. However, zero tolerance is only as good as its universal enforcement, and as the Office of Inspector General revealed in it's June 8, 1993 inspection report, that enforcement is not universally applied.

This report, completed 5 months after the Northwest outbreak reveals:

"Specifically, we found the following:

Meat products were contaminated with feces and other unidentifiable particles and, while contaminated, came in contact with other edible organs.

¹⁶ *The Epidemiology of Infections Caused by E. coli* 0157:H7, Other Enterohemorrhagic *E. coli*, and the Associated Hemolytic Uremic Syndrome, by Dr. Patricia Griffin and Dr. Robert Tauxe, CDC, AJE, 1991; 13:60–98.

¹⁷ Dr. William Keene, epidemiologist, Oregon Health Department (See Appendix I, pages 75 and 76.).

¹⁸ Dr. Tonya Roberts, USDA Economic Research Service.

¹⁹ Del Allen memo regarding zero tolerance interpretation.

²⁰ USDA's rough draft of zero tolerance initiative.

Oversized carcasses were touching contaminated surfaces, including the kill floor, and water was splashing from the kill floor onto hanging carcasses.”²¹

While in theory zero tolerance is in effect, the 47 recorded incidences of contamination of product²² in one inspection report and continued complaints by Federal meat inspector testify to the inconsistent application of the Zero Tolerance Initiative.

Labels

The inability to pass even a simple label requirement for meat products spotlights again a department unable to channel enough of its abundant resources and manpower to adequately enact change. When the USDA lost the labeling lawsuit on a technicality, we wondered, as did the court, “*Why they [USDA] waited for many months before taking any rulemaking action to deal with the problem,*”²³ and then calling it an emergency. Nor do we understand why the USDA, which began the process for issuing safe handling regulations before the *E. coli* outbreak in January 1993, was still unprepared to attempt labels until October 1993—10 months after the outbreak.²⁴

Considering the alarming contamination rates revealed in independent samplings, and the horrific consequences of neglecting to warn unsuspecting consumers about potentially lethal pathogens, we find it astounding that any industry or political figure would attempt to block labeling. Also astounding is the fact that meat and poultry inspection escape a public health agency’s oversight. Every ingestible substance in the United States is under the sole jurisdiction of a public health agency, except meat and poultry. Why the exceptions?

Announced Unannounced Inspections

Secretary Espy recently announced unannounced inspections as a continuation of special reviews. This is a step in the right direction. Last Spring’s 90 surprise inspections, resulting in 30 temporary plant closures, was a symbolic response. This action raised such “questions as, ‘Why are surprise inspections not part of standard FSIS oversight program?’ and ‘What about the other 1,100 plants?’” Unannounced reviews and financial penalties for violations must become part of a regulatory program.

Plants like Cornhusker must not be allowed to escape scrutiny any longer. The pleas from groups such as the “Omaha Thirteen” directed to FSIS can never be ignored again.²⁵ On February 8, 1993 the “Omaha Thirteen” warned FSIS management,

“Cornhusker is a “*Roach and rat-infested plant.*” They advised FSIS that the “*Plant was filthy*” and that, “*inspectors had no backing.*”²⁶

On March 25, 1993, April 8, 1993, and again on May 5, 1993, inspectors noted loads of product not in zero compliance”²⁷

We cannot comprehend why Cornhusker was not one of the original 90 plants targeted for surprise inspections. In fact, it’s hard to fathom why plants with the history of Cornhusker are still permitted to conduct business, let alone have their product stamped for wholesomeness by the USDA.

Rapid Laboratory Testing

FSIS foot dragging on microbial inspection has been maddening. We witnessed an evolution of poor excuses in the aftermath of the Jack-In-The-Box epidemic. To paraphrase FSIS defenses:

1. “*There is no tool.*” When media reported that several microbial probe technologies did in fact exist for 0157:H7, the excuse mutated into,

2. “*It will be too expensive!*” Dr. Cross cited a \$58 billion dollar figure before this Senate Agriculture Subcommittee last March. When we questioned FSIS mathematics the excuse became,

²¹ Office of Inspector General’s report to Dr. Russell Cross dated August 12, 1993.

²² Ibid.

²³ Civil Action No. A93 CA 586 JN pages 4 and 5, United States District Court, Western District of Texas, Austin Division.

²⁴ Ibid.; page 6.

²⁵ Office of Inspector General, report.

²⁶ Ibid.

²⁷ Ibid.

3. *"The existing technology is not fast enough!"* When we met with FSIS in September and discussed a 1 hour test, the excuse further mutated into,

4. *"All of the tests involve an enrichment stage. We don't want our inspectors to be exposed to the biohazard of culturing colonies of 0157:H7 in plant laboratories. They might get sick!"*

STOP! finds this rhetoric unacceptable. FSIS is charged with protecting consumer health. Thousands more consumers have been sickened, and 16 outbreaks have unfolded while FSIS procrastinates. An indicator of FSIS foot-dragging has been the tardiness of the FEDERAL REGISTER notice for technological submissions. Printed in mid-October, it came 10 months after repeated pronouncements that the search for microbial technology was of the highest priority for the USDA.

What Still Needs to be Done to Ensure a Safer Meat Supply

Commitment to public health as a number one priority

We are hopeful of an appointment of a medically trained human health expert as administrator of FSIS, not another veterinarian or industry-trained representative. This action would do much to follow through on Secretary Espy's May 27, 1993 pledge to redirect the USDA along the lines of public health. FSIS has assigned one veterinarian to the halls of the CDC (Center for Disease Control) and refers to her appointment in the context of the formation of a public health division.

As parents and friends of *E. coli* victims, we were astonished to learn that there has not been medical direction in the writing of meat and poultry inspection policy. This enormously important program has been solely in the hands of veterinarians and industry. The Agency in charge of food safety must have human health and safety foremost in all its programs. The historical and current lack of public health leadership in FSIS has caused, compounded, and tragically delayed the resolution of the *E. coli* problem.

Examine the Slaughter Practices

January 19, 1994—STOP! members again met with representatives from the USDA. We asked the same question we've been asking for a year—"What has been done in the slaughterhouse to stop fecal and ingesta contamination?". The response is always the same—no response.

Why haven't studies been done to determine what evisceration and skinning techniques cause contamination of our food supply? Are there any scientifically proven tests that demonstrate our increased line speeds are not the culprits that logic dictates they be? Dr. Cross' words to us, "Don't sweat the line speeds"²⁸ are hardly reassuring.

The USDA needs to start looking at those things that are under its control—the slaughtering, processing, and inspecting of meat and poultry. However, it has chosen to carefully avoid the slaughterhouses, and focus exclusively on the farm and the consumer's table—things over which they have no jurisdiction or control.

Serious examination of slaughter methods must include intense scrutiny of "bed slaughter"—the process of laying the animal (hide intact) on it's back on a bed of rails 8–10 inches above the floor. This process has been demonstrated to increase the likelihood of fecal contamination, and has been implicated as a possible contributor to the contamination of meat in a 1993 outbreak.

What the USDA doesn't seem to want to face are the hard questions. "Questions like, 'Why is fecal contamination increasing?'; 'What recent changes in the slaughterhouse practices have increased the likelihood of splitting the gut, and contaminating meat?'; 'What line speed is verifiably safe for what plants?'; 'How many inspectors are necessary to adequately inspect?'; "or the most basic question of all, 'Why are our slaughter practices not based upon scientific data and the dictates of public health?'"

Public Health Emphasis at the HACCP Roundtable

The Hazard Analysis Critical Control Point plan will hopefully be a tool to increase the safety of meat and poultry products. However, the proportions for constituent representation do not reflect USDA's promise to direct this agency along the lines of public health. Specifically, industry is granted five seats at the table, while public health experts are offered only two. In order to redirect this industry-

²⁸ FSIS meeting with Foundation to Eliminate *E. coli* Outbreaks in Seattle, on June 1, 1993.

entrenched agency towards public health this must be rectified immediately. The emphasis must be on public health.

Will the USDA make HACCP work by requiring its implementation framework of a regulatory program? The fate of details like public access to corporate compliance records will be very important indicators of USDA's acceptance of the responsibility for running inspection as a consumer-protective public health program.

Classify Dangerous Pathogens as Adulterants

The USDA must reclassify dangerous pathogens as adulterants. Dr. Hill Hollingsworth (FSIS) spoke the truth when she said, "We will take no action because this meat [from the Jack-In-The-Box outbreak] does not violate USDA standards²⁹. Meat that so tragically violated human health should have violated USDA standards, but it doesn't because USDA standards are woefully inadequate to protect human health. Interestingly, the meat would have violated FDA standards.³⁰ Classifying dangerous pathogens as adulterants will shorten the road to true progress, avoid endless legal battles in the future, and catch America up to this higher standard which already protects other nations.

Remove Inspection from the Marketing and Inspection Arm of FSIS

FSIS's Marketing and Inspection Department by its very name is charged with conflicting responsibilities. A department charged with ensuring industry's profits while policing its product will continue to undermine Secretary Espy's good intentions for true reform. We would not have the FDA charged with marketing drugs and inspecting them. Why then the USDA? Unbelievably, we allow these two radically opposing responsibilities to remain in the same department and title, a corruptible arrangement unique in Government oversight.

Empower Inspectors to do Their Job

An increase of 200 new inspectors was a tangible measure of change. However, there is still a way to go to fill the 550 original vacancies. The effectiveness will be determined by the answer to: "Will inspectors be empowered to enforce poultry regulations?"; "Will their agency back their dispositions, or continue to overrule their decisions after pressure from industry?"

The autonomy of this force is an unanswered question. Will inspectors outrageous reprisals, such as the April 1993 incident, when the "Omaha Thirteen" were concerned enough to contact the deputy administrator of Inspection Operations, and tell him they were threatened for "squealing."³¹

If inspectors continue to face harassment like the incident on April 6, 1993 at Cornhusker plant, any future reforms in the USDA will remain strictly on paper. The April 6 incident was:

"Inspectors noted rat droppings on the third-floor hallway. The report said the plant manager stepped on the droppings and said he did not see anything."³²

Institute Across-the-Board Microbial Testing Immediately

Microbial testing should be instituted immediately. We should not have to risk more lives while FSIS works to shave 10 more minutes off its current probe. We ask that FSIS use existing technology. What possible benefit will a 10 minute shorter wait time have on the test's ability to detect this deadly pathogen? Must we wait until FSIS refines the probe to match the 9 second per carcass line speed?

We do not naively assume that FSIS can test every piece of meat. We do however ask it to use current technology in logical and creative manners. At this point FSIS is perfectly capable of testing herds before certification for slaughter, equipment, surfaces, and certain critical control points. The Department is capable of testing random samples of a day's production before that product is shipped to consumers.

We hope the reluctance to institute this testing does not lie only in the financial issues for industry. The questions of what industry must do with such tainted product will have financial implications; however, there is no price tag on human lives and suffering.

²⁹ WA Dept. of Health notes on conversation between Bert Bartleson of WA Department of Health and Dr. Jill Hollingsworth.

³⁰ U.S. Food Legislation, Codes and Regulations, Foodborne Illness, U.S. Food Legislation, series, Authors T. Thompson, et. al., The Lancet, December 22, 1990.

³¹ Office of Inspector General's report.

³² Ibid.

Institute Research on Carcass Sprays

Carcass sprays are not a public health tool. It appears cynical that FSIS uses the Northwest tragedy to justify carcass sprays. Objections to carcass sprays are as follows:

1. We have not seen one serious scientific trial proving their efficacy. The National Cattlemen's Association or American Meat Institute research on carcass sprays is not unbiased verification, considering the added benefit to industry of added water weight sold at beef prices.
2. We know of skyrocketing *salmonella* rates under Streamlined Inspection System poultry after it was treated in similar attempts to "wash away" contamination.
3. The scientific community informs us that sprays cannot wash away contamination. They tell us sprays only scatter into unrecognizable particles and further imbed feces, milk, or ingesta into meat fibers and crevasses.
4. We observe that carcass sprays are absolutely illegal in the European community meat regulations. E.C. meat inspection officials have told us that their data discredits the safety of this practice.

In summary, carcass sprays appear to be a possible public health disaster in the making. STOP! is open to evidence to the contrary, acquired by independent scientific review of this practice.

Institute Traceback and an Effective Recall Program

Clearly define the role of FSIS personnel involvement in the investigations of foodborne illness outbreaks. We want to eliminate any appearance of obstruction in the information flow. Consumers and health departments must be assured of accurate and unbiased investigations. We also ask that the head of the Emergency Measures Department (Recall) be an epidemiologist with an understanding of the crucial public health role this position carries.

Putting consumer safety first requires traceback. Tracing contaminated product to its source creates the necessary accountability for enforcement of food safety standards. Slaughterhouses that continue to produce contaminated meat must be investigated and corrective measures put in place. Corrective measures, violations, and fines must be open to public scrutiny. Slaughterhouses that repeatedly fail public health standards must not be allowed to operate.

Don't allow USDA Usage of Irradiation

The USDA hasn't proven itself worthy of trust. According to a 1993 report the Nuclear Regulatory Commission (NRC) fined the USDA \$10,000 for repeatedly violating numerous radiation safety guidelines at more than 20 research sites.³³ This raises disturbing questions. How can consumers trust the USDA to oversee numerous irradiation facilities if it can not safely handle limited amounts used in research programs? How can we trust USDA or industry to handle radioactive materials, when it hasn't been able to manage simple fecal matter?

To Resolve the Consumer Trust Issue

Solutions to the problems of foodborne pathogens are not as USDA and the industry assert, limited by current science, but rather by USDA/industry conflict of interests. Industry has fought: labels, reduced line speeds, accountability to consumers, traceback, microbial testing, public disclosure of compliance records, and even cooking temperatures. An industry leader even questioned whether the USDA has the authority to still detain the contaminated meat. Do they want it shipped out? Better yet, would they feed it to their children or grandchildren?

Members of the committee, please listen carefully to the words of one of your constituents, Connie Tindall. She's the grandmother of three-year-old Scottie who died an agonizing death from *E. coli* contaminated hamburger this past (1993) summer in Michigan:

"I've lost all faith in the Government. When I see the American flag I cry again, to think that in this beautiful country that I love, we have such thoughtless people running it. I will never forgive them for all the pain they have caused the families affected by this. They could stop this, and yet we

³³ Article entitled *USDA Fined for Radiation Safety Lapses*, Spring 1993, Safe Food News.

*have to fight all of them. . . . I tell everyone who will listen about E. coli, and what is happening."*³⁴

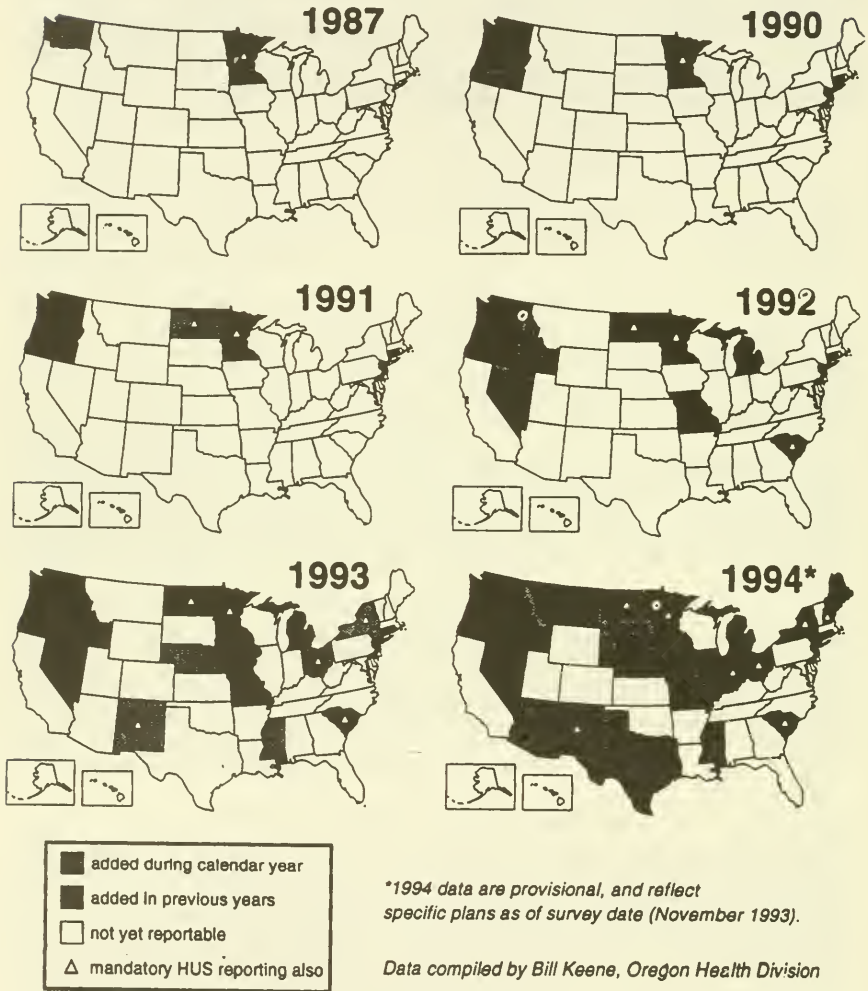
Scottie's Grandma

Unfortunately, the sentiments of Scottie's grandma are heard in too many households all across this Nation. As representatives of victims of foodborne illness outbreaks, STOP! urges this committee to hold the Food Safety and Inspection Service, of the USDA, accountable to make these changes, and hold it responsible for protecting the lives of the American consumers.

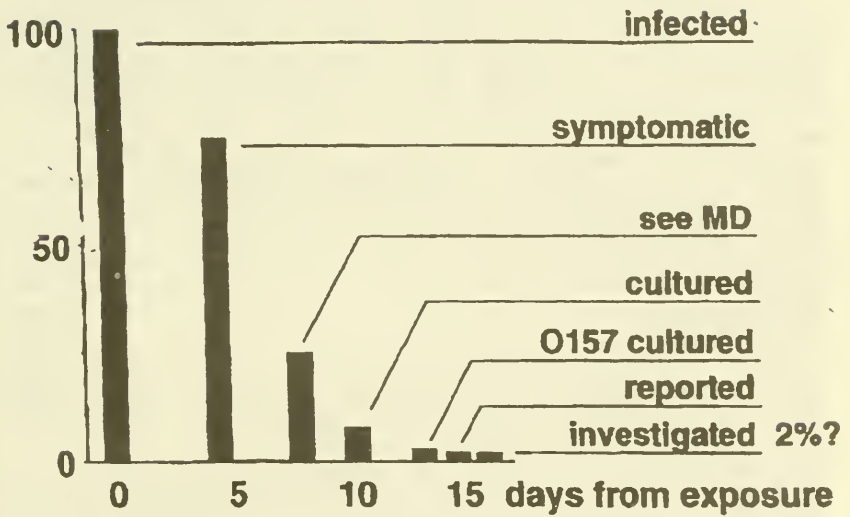
Until these changes are instituted, more innocent victims like Scottie, Michael, Kevin, and their families will pay the ultimate price for USDA irresponsibility. If FSIS will not make these necessary changes, the betrayal of our trust will leave the Department of Agriculture with the heaviest burden of all—*guilt*.

³⁴ January 1994 letter from Connie Tindall to STOP!

Spread of Mandatory Reporting Rules for *Escherichia coli* O157:H7 Infections



Reporting is Incomplete



WESTERN ORGANIZATION OF RESOURCE COUNCILS (WORC)

We would like to thank the subcommittee for the opportunity to submit testimony on a topic of grave concern to consumers and livestock producers.

The Western Organization of Resource Council is a federation of six grassroots membership organizations in Colorado, Idaho, Montana, North Dakota, South Dakota, and Wyoming. Our members are ranchers, farmers, and small business people concerned about the economy and quality of life in rural America.

As agricultural producers, WORC members realize that their livelihood depends on providing consumers with the highest quality product possible. The price they receive for their livestock is closely tied to consumers' perception of the safety and quality of the meat they purchase in the supermarket. It is livestock producers who suffer whenever unsanitary conditions inside packing plants are brought to the public's attention. What angers livestock producers is that they suffer for something they have no control over.

WORC has had a longstanding interest in preserving integrity of the meat inspection system. We campaigned to end funding for the Streamlined Inspection System for Cattle (SIS-C), which we believed damaged the image of beef. Our fears were realized when ABC's *Primetime Live* carried an expose of the conditions inside a SIS-C packing plant. Soon after, the outbreaks of *E. coli* 0157:H7 in the Pacific Northwest showed the deadly results of an inadequate inspection system.

In the year following the Jack-In-The-Box tragedy, USDA has often stated its desire to improve Federal meat inspection. However, there has been a lack of will to implement known, well understood, quality control principles in meat inspection. It may be that here has been political pressure exerted to preserve the level of production and line speeds in the largest packing plants. Some plants process over three-hundred head of cattle every hour. The current level of staffing in the Food Safety and Inspection Service (FSIS) is inadequate to handle that kind of production, without slowing down the line speeds.

Along with the examinations of beef inspection practices since the tragedy, the media has continued to scrutinize poultry inspection, which has been under Streamlined Inspection for years. It sometimes appears that the sole aim of poultry inspection is to enable poultry packing plants to run at the highest possible line speeds. The levels of pathogens such as *Salmonella* and *Campylobacter* in a raw poultry are scandalous. The slipshod inspection of poultry lowers the manufacturing cost of poultry products, increasing its cost advantage over other meat products. WORC believes that any change made in meat inspection practices should be applied equally to all types of meat.

WORC is also concerned about the safety of meat imported into the United States in wake of the North American Free Trade Agreement and the General Agreement on Tariffs and Trade. At the border crossing at Sweetgrass, Montana, one customs inspector has turned back almost a third of the trucks of Canadian beef he is allowed to inspect. What good is it to have the best inspection system possible if a flood of tainted meat washes across our borders?

Consumer confidence in the safety and wholesomeness of the American food supply is vital to the economic well being of agriculture. Meat and poultry are especially vulnerable to contamination by microorganisms that can cause spoilage or illness during slaughter and processing. Producers must rely on packers to operate their plants safely and efficiently and on the FSIS to allow meat inspectors to do their jobs. The following six principles form WORC's official position on meat inspection must be followed in any meat inspection system in order to protect producers and the public from episodes like the outbreak of *E. coli* in the Northwest last winter.

The authority of meat inspectors must not be weakened. Under traditional inspection, if a meat inspector sees a dangerous condition developing, he or she can order the plant shut down until the condition is corrected. This power is vital to balance the huge economic imperative meatpackers have to run plants at full capacity at all times to maximize profits. Indeed, the prospect of losing a few hours of production can be a more powerful deterrent to poor manufacturing practices in the meatpacking industry than fines or even imprisonment.

Inspectors must remain independent. The primary objective of the failed Streamlined Inspection System was the transfer of inspection duties from government inspectors to corporate employees. SIS was plagued with episodes that demonstrated why self-policing of industry impractical. During the SIS experiment there were a number of cases where corporate inspectors were intimidated by management and threatened with termination. In one case, it was reported that a manager actually struck one of the corporate inspectors. In another case, employees removed tags marking contaminated meat. Even when corporate inspectors were allowed to do their jobs, many were so ill-trained that they were unable to recognize hazardous

conditions or properly inspect the meat. Any new system of inspection must rely on independent, fully-trained inspectors.

Microbiological testing must not replace basic sanitation. We agree with the critics of the current meat inspection system that inspection methods need to be updated to take advantage of modern microbiological rapid testing techniques. However, testing cannot replace basic sanitation as a measure to prevent contamination.

Moreover, merely adding another layer of testing at the "end of the pipeline" flies in the face of modern quality control methods, which are based on constant monitoring of the most likely sources of contamination and strict sanitation programs to prevent contamination from those sources. Simple measures like cleaning equipment after a "gut puller" ruptures a cow's intestines or cuts into a water belly are better ways to achieve a safe food supply than testing the final product. The proper role of microbiological testing in good manufacturing practices to ensure that sanitary measures at critical points in packing process are being adequately observed.

Microbiological testing also should not be used to avoid consideration of technologies that avoid contamination hazards. For example, in Europe is cooled in a chiller room, like beef is in the United States. This avoids cross contamination that is found in U.S. poultry plants, where poultry is cooled by dunking the birds in a tank of cold water after one contaminated chicken goes into the bath, all of the following birds will be contaminated. A small independent poultry company in Kentucky was the first plant in the United States to use the European process.

Fully fund the Food Safety and Inspection Service. During the Reagan and Bush administrations, the Food Safety and Inspection Service was understaffed by more than 500 positions, leading to overwork of the inspectors on the job and many of the problems with the service we see today. The hiring of 160 new inspectors by Secretary of Agriculture Espy after the tragedy was a good first step, but problems will persist until the number of inspectors is back to full strength.

Implementation of a true HACCP (Hazard Analysis-Critical Control Points) based inspection system. Many proposals that bear the HACCP label have little resemblance to the true HACCP model. HACCP must mean identifying and monitoring all of the points in a plant where contamination can occur and maintain a high level of sanitation at those points. If contamination is found at any of the critical points, then production must be halted until the unsanitary condition is remedied. In practice, this means that packing plants will have to develop a set of good manufacturing practices to control hazards like manure buildup around machinery, inadequate sanitation of equipment, and cross contamination of carcasses, for each and every critical control point. If these practices are not followed lines must be shut down until the hazard is corrected. Any future inspection system must fully implement preventive sanitation concepts to be considered a true HACCP program.

Extend whistleblower protection to all government and private sector employees. Intimidation of inspectors and employees by management is a serious problem in the meat industry as well as many other industries. Inspectors who complained about the Streamlined Inspection System were threatened with the loss of their jobs. If it were not for the limited whistleblower protection inspectors have as government employees, we would have many more cases like the tainted Jack-In-The-Box hamburgers. No employee should lose his or her job for refusing to perform an unsafe or illegal act or reporting illegal or unsafe acts by their employer to the proper authorities.

Livestock producers have suffered greatly from the exposure of the abuses of the packing industry in recent years. From *PrimeTime Live* to *Beyond Beef* to the Jack-In-The-Box tragedy, the excesses of a few have been used to paint the entire livestock industry as anti-environmental and anti-consumer. Cow-calf producers have the least influence on what is done with the animals after they are sold, yet they suffer the most when adverse publicity damages the image of beef and causes prices to crash. We have a vested interest in ensuring those who buy our animals treat them in the most humane and safest ways possible. We therefore urge USDA, FSIS, and Congress to incorporate these principles in any modifications to the meat inspection system.

SENATOR DASCHLE'S QUESTIONS PRESENTED TO WITNESSES WITH RESPONSES THERETO

Patricia Jensen

Question 1. What specific legislative changes do you believe are necessary to ensure the safest possible meat supply?

Response. Legislative changes will be necessary to support our efforts to ensure the safest possible meat supply, particularly in the area of pathogen reduction. Secretary Espy envisions a farm-to-table strategy for food safety. The following legislative changes are part of the steps that need to be taken to accomplish our objectives.

(a) Increased authority for the Secretary of Agriculture to ensure the safest possible food supply. This would include authority: to mandate inspection changes based on new scientific and technical information as it becomes available to control pathogens; to promulgate regulations to limit the presence of pathogens in animals presented for slaughter; and to mandate on-farm practices shown to be effective in controlling pathogens.

(b) A clarification of the definition of adulteration to differentiate between raw and ready-to-eat products. Present scientific and technical knowledge (excepting irradiation which has been approved for destroying pathogens in poultry) does not provide a means to ensure that raw product is free of pathogens. Production measures can be required that will minimize and retard the growth of pathogens. However, raw product must be properly handled and cooked to ensure the prevention of foodborne illness. Ready-to-eat products must be treated to ensure pathogens are destroyed.

(c) Animal identification for traceback. On farm intervention procedures cannot be effectively targeted if animals cannot be traced to the origin farm.

(d) Mandatory recall of adulterated product. Through sections 402 and 403 of the Federal Meat Inspection Act, sections 19 and 20 of the Poultry Products Inspection Act, and regulations promulgated thereunder, FSIS has the authority to detain and seize product which it finds adulterated. However, FSIS presently has no recall authority. To recall adulterated product, industry must agree to a voluntary recall.

(e) Civil penalties for repeated inspection violations. These penalties will provide FSIS with another means of ensuring that adulterated product is not distributed. Criminal sanctions are vital in assuring the enforcement of inspection statutes, but are not enough. Criminal prosecution is a lengthy and cumbersome process in an already overburdened judicial system. These proceedings can take up to 3 years to stop a plant from operating. During this time the Agency must utilize additional inspection resources to ensure that adulterated product is not distributed in commerce. Some civil penalties, on the other hand, can be imposed administratively, insuring that the violator will be dealt with in a more timely and effective manner.

(f) Authority to conduct on-farm investigations of residues and pathogens known to cause foodborne illness to humans. Current statutes only permit the Animal and Plant Health Inspection Service (APHIS) to go on the farm to look for animal disease causing pathogens.

Question 2. During last February's hearing, we were told the time frame for Track II reforms was 2 to 3 years. Can we still expect to see a completely new, science-based system of meat inspection and safety in place within 2 years from today? If not, what is your revised time frame for implementation of Track II?

Response. Track I is designed to maximize the performance of the current inspection system. These activities and the time frames for implementation have been identified and were presented in charts to the Subcommittee on February 10, 1994. The long-term revolutionary Track II effort must operate on a separate track from the short-term evolutionary Track I because of the inherent differences in the two approaches. The Agency, however, is pursuing the two approaches concurrently. That means FSIS is moving to improve the current meat and poultry inspection system while preparing for the inspection system of the future.

FSIS has set as its goal to become a science and risk-based system by the year 2000. The 2- to 3-year Track II time frame referred to is for developing a framework for this system. The framework will identify the types of inspection activities that should be part of the new program and will document the need for them. It will contain recommendations for what parts of the program can be implemented immediately and what will require gradual implementation. It will identify the resources and any changes in the law that are needed, as well as the research and other exploratory work necessary to support the program.

The Track II activities that will produce the framework are proceeding on schedule and are expected to be completed by the end of 1995. As the first step under Track II, FSIS conducted a series of six public hearings last summer to hear the opinions and views of as many people as possible on the Agency's plans for improvement. In November, the Agency sponsored a conference on the Regulatory Program of the Future attended by consumer groups, labor representatives, public health officials, industry, and academicians. The World Congress on Meat and Poultry Inspection, cosponsored by FSIS last fall, brought together international experts in the

fields of meat and poultry science and inspection technology. Information from these meetings and other sources will be incorporated into the design phase of Track II. Broad constituent involvement and consensus will be sought on the Agency's proposal, and new components of the program will be pilot tested. It is likely that new legislation will be required. No exact timetable can be set until we better identify the activities to be implemented.

Reference. I congratulate USDA for forming the Pathogen Reduction Task Force. Interagency cooperation will be vital to our efforts to improve food safety. However, I do not understand why it took over a year from when this task force was first recommended to conduct the first meeting.

Question 3. Can you explain why this took so long?

Response. Since Secretary Espy took office last January, the focus has been on getting our Marketing and Inspection Services' pathogen reduction activities implemented. The previously mentioned charts that were submitted at the February 10, 1994 Subcommittee hearing detail the status of over 70 of these activities. Cooperation with other agencies is an integral part of many of these activities. The plan for creation of the Task Force was submitted to and approved by the Secretary in November 1993.

Interagency cooperation is vital to our efforts. During the past year USDA agencies have worked closely together. This task force will continue that cooperation through a more formalized mechanism. It is meant, not to institute cooperation, but to continue the momentum already underway. The activity charts identify intradepartmental pathogen reduction projects where, FSIS, APHIS, the Agricultural Research Service (ARS), the Cooperative State Research Service (CSRS), and the Extension Service are currently cooperating. Beyond the Department, USDA and FDA are cooperating, particularly in educational activities. For example, in 1994 we jointly sponsored a teleconference for state health officials to discuss the *E. coli* outbreaks and initiated the promotion of the new Food Code. The Centers for Disease Control is another important partner. FSIS has detailed a liaison officer to the Centers for Disease Control (CDC) to assist in the investigation of foodborne outbreaks and to help integrate food safety issues into planning and day-to-day operations at CDC. Both FDA and CDC will have representatives on the Pathogen Reduction Task Force. As I indicated, the Task Force formalizes relationships that are already established.

Reference. Last year, Secretary Espy told us he would move "right away" to make improved recordkeeping and traceback a standard throughout the industry. The National Cattlemen's Association tells us that only minor improvements are needed to make this happen. Yet, your testimony indicated that USDA's traceback system will not be implemented until 1995.

Question 4. Why will this take so long?

Response. The proposed rulemaking to mandate improved recordkeeping in plants should be published in the *FEDERAL REGISTER* within the next months and we hope to make it effective later this year. The regulation now under review within the Department can only impose recordkeeping requirements on Federally inspected establishments. The establishments can be directed to maintain records identifying their immediate suppliers and customers. Since animals brought to slaughter can be bought and sold numerous times, mandated recordkeeping for establishments will often not allow FSIS to identify the farm of origin. The Department will be seeking a legislative change this year to give the Secretary the authority to mandate recordkeeping by all persons involved in the commercial chain stretching from the farm to the slaughterhouse.

The responsibility for conducting traceback investigations lies with the Department's Animal and Plant Health Inspection Service (APHIS). The ability to trace contaminated meat or an infected animal back to the farm of origin is dependent upon sound animal identification. This is a good example of a preharvest food safety activity.

One reason for the delay in implementing a standardized traceback system is the great diversity of identification methods currently used in the livestock industry. Commonly used identification methods include back tags, ear tags, bar codes, tattoos, and branding.

Complicating matters are the number of points along the food continuum where the animal or product is identified a second or third or fourth time, often confusing the original marking. In other cases, identification devices either have fallen off or were never applied. These elements combine to create an obviously disorganized chain that is difficult for traceback investigators to follow, and make establishing a national standard dependent upon long-term cooperation and commitment from

all parts of the livestock industry. It is one of our long-term goals because it will make traceback investigations easier, faster and more accurate. APHIS has formed the Electronic Identification Committee, whose goal is to establish standards for electronic animal identification devices and explore ways to reduce the cost of these potentially useful tools. Also, APHIS is in the process of soliciting applications for a National Swine Identification Coordinator. We expect the position to be filled in about 2 months.

In the 1995 Fiscal Year budget, APHIS is requesting \$5.7 million for preharvest food safety activities, and this includes resources that will be used to further develop and improve the traceback system.

Question 5. What specific role do you envision for rapid tests for *E. coli* and other pathogens in the Track II program?

Response. Rapid tests for *E. coli* would be used by inspectors in plants both to test meat and poultry for the presence of pathogens and to verify that the slaughter and processing procedures are being carried out under the best sanitary conditions available. Secretary Espy recognizes that in-plant rapid tests would represent a breakthrough in our ability to further protect the public health and has the Department pursuing the development of rapid tests on several fronts. ARS scientists have determined that a commercial bacterial test can be adapted to confirm high levels of microbial contamination on meat carcasses. FSIS and ARS are evaluating the test and striving to reduce the time it takes to perform the test, which now is about 50 minutes. The Department actively solicits help from private industry and has published its criteria for rapid tests in the FEDERAL REGISTER.

FSIS already samples production lots of ready-to-eat meat and poultry products produced at Federally inspected establishments for the presence of pathogens. Examples of such products are hot dogs, lunch meats, corned and roast beefs, and chicken salad spreads. When a sample is determined to have pathogens present, all product from the lot from which it was taken is considered to be adulterated. Unfortunately, due to current scientific and technologic limitations, several days pass between the time of sample collection and final laboratory analysis. Safe, inexpensive, rapid tests for pathogens would allow FSIS inspectors to sample a greater number of lots. Quick, in-plant results would ensure that contaminated product was not introduced into commerce—avoiding the need for a recall.

Reference. Certain problems with inspection of imported meat have been brought to my attention. Specifically, I am told that random inspection is not being done at some border inspection stations, because the facilities do not exist to unload truckloads of hanging beef shipped from Canada. Also, I am told that uninspected Australian beef products, including ground beef, is entering the United States in excess of the quota by passing through Canada.

Question 6. What is USDA doing to address this problem?

Response. Canadian carcass shipments are not staged for random selection of samples. Carcass samples are selected from the back of trucks entering from Canada. The Agency is concerned that this sampling procedure may not be statistically defensible.

Secretary Espy and Canada Minister of Agriculture Goodale held discussions in Toronto, Canada on January 8, 1994. The Secretary and Minister agreed that a joint U.S.-Canada Technical Working Group would explore options relative to import inspection of red meat carcasses. The Technical Working Group will report their findings and recommendations to the Secretary and Minister no later than April 15, 1994. In a letter to Minister Goodale following the January meeting, Secretary Espy reaffirmed his commitment to instituting a random sampling plan and maintained that such a proposal is fully consistent with obligations under the North American Free Trade Agreement.

Questions related to excess importation of Australian beef and other tariff issues are handled by the U.S. Customs Service. FSIS inspection personnel who encounter suspected violations refer these incidents to the U.S. Customs Service for investigation.

Reference. Many of the reforms proposed by USDA last February involve research. Although a number of research projects have already been launched, others have not, including your study to identify risk factors for *E. coli* contamination during the slaughter process. This would seem to be a very critical study.

Question 7. What is the major cause of the delay in starting this study?

Response. I couldn't agree more that the information we gain from studies about risk factors for contamination during various phases and under varying conditions of slaughter and processing operations is very critical. FSIS has recently completed

the process of identifying and prioritizing the research projects needed through outside contractors. Requests for Proposals (RFPs) are now being prepared, and we expect to make these contract awards by this summer.

For Fiscal Year 1995, \$1.25 million has been requested for additional contract studies. Of this \$1.25 million, \$250,000 has been earmarked for the University of Maryland Eastern Shore, which is slated to become the Center of Excellence for Food Safety and Animal Health Research.

Question 8. Are the research initiatives, outlined in material you provided, conducted in cooperation with ARS? How do these two agencies cooperate? How responsive is ARS to your research priorities? How much of the ARS fiscal year 1994 budget will be used for research on food safety?

Response. Some of the research initiatives will be conducted in cooperation with ARS, some will be competitively awarded using either contracts or cooperative agreements; some will be conducted by industry or academia; and some will be done in-house by FSIS laboratories. ARS and FSIS cooperate through a Memorandum of Understanding that was first instituted in 1981. For more than a decade, FSIS scientists have presented research project proposals to ARS through the formal mechanism of the Annual Food Safety Workshop, usually held during the first week of December. Prior to the formal presentation, FSIS and ARS scientists collaborate on what research has an immediate priority and where, within ARS, the research might be conducted. Twice a year, ARS submits to FSIS a written summary of the research results and publications stemming from those projects.

ARS has been very responsive to research proposals that are presented to them by FSIS. ARS primarily views its emphasis as more fundamental and applied research, whereas often FSIS needs methods research. While FSIS fully supports the need for and validity of basic, long-term research as an investment in the future, FSIS will continue to have a need for research results that answer questions and help in the short-run. The total food safety research budget for ARS in fiscal year 1994 is \$37.5 million. Roughly one-quarter of that budget will support FSIS in its Pathogen Reduction Program activities. The Pathogen Reduction Task Force, which I mentioned earlier, will further strengthen the cooperation between ARS and FSIS research needs in the future.

Carol Tucker Foreman

Question 1. What specific changes do you believe are necessary to ensure the safest possible meat supply?

Response. The Safe Food Coalition believes the following statutory changes are necessary to ensure the safest possible meat supply:

- Declare that the purpose of meat and poultry inspection is to protect public health.
- Move meat and poultry inspection from USDA and place it in a public health agency, either the Department of Health and Human Services or an independent food safety agency.
- State specifically that raw meat and poultry are adulterated if they contain levels of pathogenic bacteria which may be hazardous to human health and require that USDA set guidelines for maximum acceptable levels of pathogenic bacteria.
- Require USDA to contract with FDA to set guidelines for maximum acceptable levels of pathogenic bacteria in both raw and processed meat and poultry products. Require USDA to submit results of baseline microbiological studies to the NAS Food and Nutrition Board for review and determination of appropriateness before they are used.
- FSIS or a new food safety agency needs statutory authority to regulate the safety of meat and poultry products from the time that animals are raised on farms to the time that these products are sold to consumers. To meet these ends, an animal identification and traceback system should be mandated.
- FSIS or a food safety agency should have authority to issue regulations that would require good animal husbandry practices on farms; and it should have the authority to inspect farms to assure that these regulations are followed.
- The Federal agency in charge of food safety also needs statutory authority to issue regulations that would assure the safety of meat and poultry products while they are being shipped and while they are in storage.
- FSIS or a new food safety agency needs statutory authority to mandate the recall of adulterated products.

- FSIS or a new food safety agency must have authority to impose civil penalties on companies that violate inspection regulations or laws.
- If plant employees replace Federal inspectors in providing public health protection, they must be assured whistleblower protection. They must be assured that they will not lose their jobs when they report public health hazards.

Question 2. In the past, the Safe Food Coalition has called for a HACCP system with uniform standards across the food industry. Does this mean that the same set of procedures should be mandated for all livestock classes, and all types and sizes of slaughter and processing facilities? Or should HACCP plans be tailored to each situation, according to specific conditions that pose the greatest hazards?

Response. The goal of a safety-based HACCP system is to prevent problems from occurring by controlling the points at which health hazards may arise. A HACCP plan, therefore, must be shaped by the processes being carried out and would not be uniform in all plants.

While identical procedures across the board are not rational in HACCP, USDA must establish maximum acceptable levels of bacterial contamination for all products and apply it across the board.

We cannot imagine that any meat processor, the Senate or the public would find it acceptable for Plant A to have a HACCP plan that enables it to regularly produce products with bacterial counts below a Federal guideline and Plant B to have a HACCP plan that regularly turns out the same products but with very high rates of bacterial contamination.

If the goal of HACCP is to control hazards, there must be measures of the effectiveness of a HACCP plan. Maximum acceptable levels of microbial contamination must be one of those measures.

Reference: Some groups have criticized the current meat inspection system as having very little to do with human health.

Question 3. How do you see the current system of organoleptic inspection of each carcass fitting into the new, science-based meat safety program of the future?

Response. The 1985 NAS report stated that the present organoleptic inspection system has been reasonably effective in preventing apparently diseased animals and visibly contaminated products from being distributed. In addition, USDA plant sanitation requirements probably reduce disease causing bacteria.

The Safe Food Coalition wants empirical evidence that any new system is producing meat and poultry that are cleaner and safer than those produce by the present system. The public has a right to expect that a "science-based system" can meet the first requirement of science . . . empirical evidence.

The public also has a right to expect that a new system will provide a higher level of safety, i.e. less bacterial contamination, than the present system. Finally, we will continue to support the present level of continuous inspection until HACCP is in effect, proved to produce safer product and an appropriate regulatory program is established to work within a HACCP system.

There should be public availability of all plant HACCP plans and records relating to the HACCP plan and all actions taken by Federal inspectors to enforce safety in HACCP plants. USDA's HACCP might constitute a massive "privatization" of a previously public function. Under the present inspection system, Federal inspectors review plant operations each day and then sign an inspection report. The report notes any problems which had to be remedied to produce safe product and is available to the public. The NACMCF recommended that HACCP plans "must be considered proprietary information that must not be made available outside the regulatory agency." (Generic HACCP for Raw Beef, p. 36). FSIS should not follow this recommendation. The plans must be publicly available.

Reference: Your coalition has proposed mandatory good husbandry practices on farms, if and when such practices are developed. How do you propose that such practices should be enforced?

Question 4. If changes in on-farm infrastructure are necessary, who should bear the cost of implementing them?

Response. The NAS recommended that changes be made in animal husbandry practices in order to reduce contamination of animals and birds arriving at the slaughterhouse. Other countries have required such changes as pasteurized feed to avoid recycling bacteria and preslaughter sampling of flocks to detect those with high levels of contamination. It may be appropriate for government to offer incentives to producers to make the changes necessary. Any costs associated with changes in production and processing should be weighed against the present costs, estimated by GAO to range between \$17 and \$23 billion annually, of foodborne illness.

Reference: Your organization calls attention to the need to greatly reduce, if not eliminate pathogen levels in meat and poultry products. We have heard about research into some technologies that may be able to significantly reduce pathogen counts, such as carcass sprays, vaccines, feed additives, electron beam treatment, light impulse treatment, genetically-engineered resistance, biological control, and, perhaps the most controversial, irradiation.

Question 5. Do you support research and development of these and other such technologies?

Response. The Safe Food Coalition supports research into a range of methods to reduce bacterial contamination. We have suggested that the President's science adviser set up a task force to set priorities for research and to make sure that we bring to bear the widest possible range of government talent to achieve the goals. We believe that the effort must begin with what makes humans sick and work back to changes in production and processing that will result in products that are less likely to cause disease. This approach will be most successful if it calls on a wide range of experts, both in and out of government.

Reference. You have suggested that USDA should delay implementation of a HACCP program until they can prove, without a doubt, that it will make food safer than under the current system.

Question 6. Do you have any suggestions about how to prove this?

Response. In 1985, the NAS urged USDA not to make major changes in inspection "until they have been validated by objective assessments of their health impact or until their continuing health impact after adoption can be evaluated against some reasonably objective criteria. This development of criteria, or even of proxy criteria, is a prerequisite to setting any new objectives for FSIS, (p. 151)."

Given the financial and human toll of bacterial foodborne illness, we believe USDA should be eager to prove to the public that the change the Department proposes will be better than the present system. If the Department makes the change to HACCP and foodborne illness continues to increase, the Department will surely lose whatever credibility it now has.

The present system of inspection is clearly not good enough to reduce the human toll of foodborne illness. Surely no one would advocate that the Government spend and require companies to spend the enormous amounts of money required to implement a HACCP system without assuring that the proposed system will be better than the present system.

We do believe there should be, at a minimum, pilot studies and avouchment by a qualified third party, such as the HAS, that the USDA HACCP regulations will assure that plants produce meat and poultry products that meet USDA established guidelines for maximum acceptable levels of bacterial contamination.

Question 7. What would be the cost of micro-testing at the level you would recommend? Where would those tests be conducted?

Response. The Safe Food Coalition believes that USDA should set guidelines for maximum acceptable levels of microbial contamination in raw meat and poultry. We believe microbial tests should be used by plants to verify that the plants' critical control points are, in fact, under control, and the HACCP plan is working as expected. In addition to reviewing the results of those tests, USDA should perform its own tests on a random sample basis to determine that a plant's HACCP system is working.

Finally, we believe both plants and USDA should use microbial tests to sample finished products to assure a HACCP plan is producing products that meet Federal guidelines.

Many plants now test for bacteria levels. Some do not and they would have to assume these costs as part of their HACCP plan. Federal costs would depend on the frequency of the tests performed by inspectors.

Given the fact that USDA now spends over \$500 million a year of our tax dollars on a system which is generally recognized to be unable to control bacterial contamination, and that GAO has estimated the cost of foodborne illness to be between \$17 and \$23 billion a year, it is likely that microbial tests would not be cost efficient.

Reference: During the hearing last year, we had a discussion regarding labeling of food items containing toxicant. You indicated in the discussion and in your letter to me, following the hearing, that "I think it is inappropriate to label raw meat and poultry as 'wholesome' when they contain pathogenic bacteria."

In the February 1993 American Medical Association publication, *ARCH FAM MED/ VOL 2*, it states that:

"Many food sources contain toxic substances of one kind or another. For example, certain mushrooms are poisonous. Cashew nuts, apricot kernels, and lima beans contain cyanide. Sassafras teas and many spices contain the carcinogen safrole. Nutmeg contains a potent hallucinogen, and potatoes contain low levels of solamine. People have learned to live with these toxicants by avoiding poisonous varieties (e.g., mushrooms), limiting consumption to subtoxic levels (e.g. nutmeg), cooking properly (e.g., lima beans), or simply ignoring the toxicant (e.g., safrole in several spices). Except for an occasional accident with poisonous mushrooms, we hear little about illnesses resulting from the consumption of poisonous plants."

Question 8. How do you believe we could address these issues in the context of the labeling recommendations you have made?

Response. The article notes that human illness resulting from the consumption of poisonous plants seems to be relatively rare. On the other hand, human illness from consuming food contaminated with pathogenic bacteria is common. The Centers for Disease Control report that there are between 6.5 and 80 million cases and 9,000 deaths per year from foodborne illness. Most of the illnesses are caused by pathogenic bacteria and foods of animal origin are the most frequent sources of the illness. The GAO has testified that these illnesses cost from \$17 to \$23 billion per year in medical costs and lost productivity. We believe the USDA has done the right thing in requiring handling instructions on meat and poultry products to help reduce this toll.

We also believe it is inappropriate for the U.S. Government to mislead the public by asserting that raw meat and poultry are "wholesome" when, in fact, USDA acknowledges that raw meat and poultry are frequently contaminated with disease causing bacteria.

The U.S. Government spends over \$500 million of the taxpayers money each year to run an inspection system from slaughter to final processing that does not work as well as it should. Raw meat and poultry that have been inspected under this system and stamped "wholesome" are often contaminated with pathogenic bacteria. Often that bacteria multiplies when the food is not handled carefully during distribution and sale. We support a meat inspection system that will reduce the level of pathogenic bacteria leaving Federally inspected plants. We also agree that it would be worthwhile to improve control of food storage and food preparation. We support improved inspection of the kitchens of commercial food establishments and retail outlets. We also support improved education of commercial food handlers and information and education efforts to improve public knowledge of safe handling techniques.

We believe USDA must set guidelines for acceptable levels of bacterial contamination of raw meat and poultry. Plants with HACCP programs in effect should utilize microbial testing to verify that critical control points are under control and to verify that final product is within the guidelines. Plants should conduct these tests on a statistical sample of product each day. USDA should use plant records to determine that the plant is in compliance and, in addition, conduct its own tests on a regular basis. Most sophisticated meat and poultry plants already conduct microbial sampling to ensure appropriate shelf life. We believe the tests should be extended to protect human life. It is unlikely that doing so would add substantially to the costs of tests the plants already conduct. The costs of tests performed by Federal inspectors could be substituted for other functions now conducted by Federal inspectors which have no relationship to human health.

Whereas the cost of testing would not be a great new cost, it is likely that some plants are now producing product that would not meet reasonable microbial criteria. Improving their product safety might be costly. We believe it would be much less costly than the toll from foodborne illness.

Question 9. When you were Assistant Secretary at the USDA, how did the Department test and remove microbiologically contaminated meat and poultry from the food supply?

Response. I served as Assistant Secretary for Food and Consumer Services from 1977-81. I had responsibility for meat and poultry inspection. At that time, USDA took the position that meat and poultry inspection were more appropriately considered consumer services and should not be combined with marketing responsibilities.

When I was at USDA there was little recognition of the extent of bacterial foodborne illness. In fact, there are indications that bacterial foodborne illness has increased in the last 12 to 15 years due to changes in food processing and consumer

purchasing and eating habits. When I left USDA in early 1981, some of the bacteria that are now frequently implicated in foodborne illness were not yet known to be harmful to humans. Some strains of *salmonella* were a well known problem, but there had been no documented cases of human illness from *campylobacter*, *listeria monocytogenes* or *E. coli* 0157:H7.

The first step toward dealing with the problem of bacterial foodborne illness was the convening of an advisory committee on *salmonella* which issued its report in 1980. Four years after I left USDA, the National Academy of Sciences, in its report, *Meat and Poultry Inspection: The Scientific Basis of the Nation's Program*, became the first group to discuss the problems of microbial contamination of meat and poultry extensively and to recommend changes in inspection that would reduce the problem. The NAS recommendations form the basis of my own and the Safe Food Coalition's advocacy in this area.

Finally, it is worth noting that before and during my tenure at USDA it was the Department's position that raw meat and poultry contaminated with pathogenic bacteria are not adulterated within the meaning of the inspection statutes. The Department has not, to my knowledge, changed that position. As a result, the Department does not test for microbial contamination in raw products. I have long found that to be a questionable position and, have sought the opinion of leading attorneys in the field as to whether it seems to be supportable. I have attached memoranda from eminent counsel saying it is not.

Reference: You pointed out in testimony before Rep. Towns' Subcommittee last November 4, that poultry contamination with feces is being labeled "inspected for wholesomeness." This is hard for consumers to understand. Having been the Assistant Secretary for Marketing and Inspection Services maybe you can shed some light on how this situation can exist.

Question 10. With all due respect, did not the same situation exist when you were at USDA?

Response. USDA should not mislead consumers by stamping contaminated poultry with a seal that says it has been inspected for wholesomeness. I regret that I did not have the knowledge or wisdom to change the practice while I was Assistant Secretary. Had I had the benefit of the 1985 National Academy of Sciences report, I would have acted on its recommendations. As noted in my answer to the preceding question, my tenure at USDA preceded the time when the Centers for Disease Control had reported extensively on the very high toll of bacterial foodborne illness. There is a possibility that some of the increase in foodborne illness has resulted from industry and consumer practices that have become more common since I left USDA. USDA research and regulatory scientists had not recommended major changes to decrease the incidence of pathogenic bacteria. USDA attorneys maintained then, and now, that the Department does not have the authority to regulate pathogenic bacteria in raw meat and poultry.

Question 11. Everyone would like to see rapid tests to detect pathogens on-line in meat and poultry processing plants. How should this research be funded? Should this be funded directly by taxpayer money, that is should USDA be doing all the research? Isn't there a tremendous economic incentive for private industry to do the research? Is USDA going about this wrong by conducting their own research and publishing criteria for rapid tests in an effort to stimulate research by others?

Response. The Safe Food Coalition strongly supports expanding the pool of scientists seeking rapid microbial tests. The National Academy of Sciences' 1985 report on meat and poultry inspection was critical of the lack of communication between FSIS staff and the larger scientific community. We are eager to tap the knowledge of scientists from across the Government to deal with the problem. Our Coalition's paper, "Reinventing Meat and Poultry Inspection," issued in August 1993 urged that the President's science adviser convene a panel of the Government's most talented scientists from the Department of Defense and NASA as well as NIH, and HHS to deal with the problem. We have thought it might be possible to adapt technologies originally developed to prevent or detect germ warfare attacks. We would be delighted to have the doors opened to private investigators as well. It certainly seems reasonable that a quick, simple test that can be used effectively in plants under common production practices could be very profitable.

Question 12. Does the lack of a rapid test for *E. coli* 0157:H7 in the medical community suggest that this really is a tough problem to solve?

Response. Despite the fact that the 1985 NAS report recommended that USDA develop rapid tests for a range of pathogenic bacteria, to our knowledge there has been no substantial effort either inside USDA or within the Federal Government to develop such a test. We are not aware that USDA has reached out to the wider

scientific community, such as private universities or research institutions, seeking such a test. USDA did not even publish the criteria for an acceptable test until last fall. We believe the lack of action until recently is a reflection of the Department's regrettable position that pathogenic bacteria are not adulterants in raw meat and poultry. If pathogenic bacteria are not viewed as adulterants, there is little reason to find methods to detect them.

Question 13. Can you appreciate the problems with establishing infectious dose levels for pathogens? Please share them with us.

Response. Determining infectious dose levels is not an easy scientific problem. However, the 1985 NAS committee, which was composed of individuals with impressive scientific credentials, stated that USDA should already have had infectious dose data for common pathogenic bacteria. USDA ignored the recommendation and we are all paying the price. fiscal year 1995 marks the first year the Department has included a budget item for risk assessment. It is only \$150,000 out of a budget of over one-half billion dollars. At this rate, we can be sure the Department will not find the answers in our lifetimes. The Safe Food Coalition has recommended that the work be funded by USDA but undertaken by scientists who are oriented to human rather than animal health issues. The Food and Drug Administration sets acceptable levels for animal drug and pesticide residues in meat and poultry. It seems reasonable to have FDA take the lead in seeking infectious dose data and setting guidelines for acceptable levels of contamination.

Question 14. What would be the implications for the meat and poultry industry of establishing a zero level for pathogens on all meat and poultry products?

Response. USDA now has a zero tolerance for pathogenic bacteria in ready to eat meat and poultry products. The Safe Food Coalition has not advocated a zero tolerance for pathogenic bacteria in raw meat and poultry. We believe guidelines based on infectious dose data would be more reasonable. Many plants now test their products extensively and have their own standard for acceptable levels of contamination.

Other plants have virtually no control on bacteria levels. Products from both the high standard and no standard plants receive the USDA "inspected" seal. We fail to understand why that is reasonable or fair to either consumers, who have no way of determining which products have low levels of contamination, or to the processors, who pay to produce a clean product.

The cost of this system is high. USDA is spending over \$500 million of our tax dollars for a system that tends to subsidize plants that produce the lowest level product. Further, GAO has testified that the direct and indirect costs of foodborne illness run between \$17 and \$23 billion a year. We think a system of bacterial guidelines for raw meat and poultry would lower the cost.

Question 15. What assurance can you give to consumers that a micro-test will prevent the spread of harmful bacteria?

Response. Once again, our position favoring rapid tests for microbial contamination is based on the 1985 NAS report. The NAS committee believed that rapid tests for microbial contamination are an important element of a science based meat and poultry inspection system. Rapid tests are an important means of making certain that a HACCP system is succeeding in keeping harmful bacteria below levels which are likely to result in human illness.

J. Patrick Boyle

Question 1: What specific legislative changes do you believe are necessary to ensure the safest possible meat apply?

Response: The end result of legislation to reform and modernize the Federal meat inspection system should be the establishment of a science-based food production system that eliminates, prevents, or reduces microbiological, chemical, and physical hazards that may endanger human health and which establishes severe penalties for individuals or firms that intentionally produce, process, or distribute products that endanger human health.

Reference: I have heard conflicting reports on the effectiveness of organic acid sprays and carcass washes in reducing pathogens. Some say they are effective, while others contend that they spread contamination and embed pathogens into the meat.

Question 2: What is your view on the effectiveness of carcass sprays? To what extent are organic acid sprays being used now? How much has their use increased since last February? How do you view the idea of mandatory use of carcass sprays?

Response: Research has clearly shown that organic acid sprays are effective in reducing pathogens on carcasses. A 1991 study at Texas A&M University to review the scientific literature on organic acid sprays was provided to USDA in 1992 and a copy is attached for your information. USDA's decision to allow organic acid sprays for beef carcasses was based largely on acid sprays result in the embedding of pathogens, and when you consider that the process consists of a light spray or mist, it is difficult to imagine how embedding could occur.

Due to the low incidence of *E. coli* 0157:H7 on beef carcasses, most of the research on organic acid sprays has focused on other pathogens. However, some work has been done on beef inoculated with *E. coli* 0157:H7, and the results are mixed. It seems that organic acid sprays are less effective on this pathogen and some additional treatment would be needed to destroy this pathogen. Preliminary results suggest that spraying carcasses with a dilute solution of Tri-Sodium Phosphate (TSP) is more effective in reducing *E. coli* 0157:H7. The Foundation is currently conducting research to identify the optimum spray system for reducing a full range of pathogens on beef carcasses.

Our industry only received permission from USDA in November 1992 to use organic acid sprays. Since that time, more than two dozen large and small plants have installed equipment and are using organic acid sprays. Since February 1993, the installations of organic acid spray systems has increased and the limitation today is availability of equipment.

If organic acid sprays and/or other intervention techniques are shown to be necessary to prevent pathogen contamination, then they should be required as critical control points in a HACCP system.

Reference: As I understand it, you are supportive of HACCP systems for meat production and processing, but you think each facility should have the flexibility to design its own HACCP program.

Question 3: If each system is different, how can we be sure that the meat released from all facilities will be equally safe? How do you propose monitoring these different HACCP systems?

Response: HACCP systems should be specifically designed for individual production processes. Consistency in those systems is achieved by verifying that they meet certain minimum standards as defined by the national Microbiological Advisory Committee and conform to the principals outlined by that same committee for developing and operating HACCP programs.

The Government's role in verifying that the systems are designed properly and operating effectively means that all systems will meet minimum standards. We believe the Government has a significant role in monitoring the different HACCP systems, but each HACCP plan should be specifically designed, by the company, to fit the products and processes unique to each in a particular plant.

Question 4: Do you think rapid tests for pathogens should be incorporated into a HACCP program? If so, how?

Response: Rapid microbiological tests play a valuable role in verifying that a HACCP system is working properly. For example, once critical control points are identified and implemented, microbiological testing is a useful tool for determining that these CCPs are effectively preventing contamination.

Microbiological testing does not in and of itself make food safe. Testing as a means of sorting contaminated product from contamination-free product does not work, because to be effective, virtually all of the food has to be tested. With a pathogen like 0157:H7, the incidence is so low (0.2 percent), that no testing program will be sufficient to find it and remove contaminated food. What makes food safe is a safe manufacturing process (i.e., HACCP). Microbiological testing is only effective in verifying that safe manufacturing process.

Reference: Your written testimony mentioned that processing plants can implement HACCP systems immediately, but that slaughter plants will take longer.

Question 5: What percentage of meat processing plants have already adopted HACCP programs voluntarily? How much time will slaughter plants need to adopt HACCP procedures?

Response: A majority of processing plants have some form of HACCP program in place to verify that process control is being achieved. All plants must in some way control their processes. In contrast to pure process control, HACCP programs add an element of risk assessment that some plants may not quantify today, but deal with strictly on a qualitative basis.

In processing plants inspectors are not an integral part of the production process, but only inspect various elements of the plant for sanitation, product standard compliance, and a variety of such issues. The difficulty in implementing HACCP

programs in slaughter plants is not with the plants because many slaughter plants currently operate with very sophisticated HACCP programs. The question is how USDA will monitor those programs since inspectors in slaughter establishments perform on-line inspection duties on each carcass. The nature of inspection and how these systems will be verified needs some additional study.

Programs such as the Streamlined Inspection System for poultry and the pilot programs that were conducted for pork and beef are excellent examples of how HACCP systems can operate in slaughter facilities. The time frame to implement this can be much shorter if there is general agreement that inspection personnel must adjust their current day-to-day activities.

Question 6: *We all hope that implementation of a HACCP program will prevent any future outbreaks of illness from contaminated meat.* But in the event that contaminated meat is identified, do you agree that USDA should have the authority to trace the source of contaminated, and recall any products that they aspect may be contaminated?

Response: AMI has consistently been a leading proponent of livestock traceback systems that include animal identification. We originally petitioned the USDA for an animal identification program to control chemical residues several years ago.

We continue to support these efforts.

Regarding the recall of products suspected to be contaminated, that can and does occur today. Plants will recall product that is suspected of being contaminated. To our knowledge, no product is allowed into the marketplace with known contamination. USDA can seize product that is adulterated or misbranded.

We do not believe, however, that all raw agricultural products should be deemed adulterated or contaminated because they may contain pathogenic bacteria. Raw agricultural products, in their natural unprocessed state, will have some incidence of pathogenic bacteria. Although that incidence may be extremely low, consumption of raw agricultural products without proper handling and preparation can create problems. But we know of no foolproof method to assure a pathogen-free raw meat and poultry supply today. Therefore, raw meat and poultry should be considered safe and wholesome if properly handled, cooked, prepared and consumed.

Reference: You have discussed some research that your industry is conducting on new technologies to reduce bacteria in meat.

Question 7: To what extent is your industry cooperating with USDA on this kind of research? How do you think USDA should proceed with the information gained from this research?

Response: The AMI Foundation and other industry organizations are aggressively pursuing food safety research designed to prevent contamination of meat and poultry products or eliminate any contamination that may occur as part of the slaughter and processing processes. We keep USDA informed on the progress of our research and strongly believe that good science should drive the policies at FSIS. At some point, the research that is under way will provide a clear direction for industry and government and will result in the implementation of HACCP critical control points which minimize or eliminate pathogens in beef. USDA's role should be to support the implementation of HACCP and monitor the effectiveness of critical control points in the manufacturing process.

Dr. J. Glenn Morris, Jr.

Reference: Your testimony emphasized the clear need for new legislation.

Question 1: Can you give me some specific details on what should be included in this legislation?

Response: There needs to be new food safety legislation that 1) removes the requirement for carcass-by-carcass inspection; 2) focuses specifically on safety considerations and prevention of disease, rather than on more general quality issues; 3) permits the implementation of modern inspection approaches and techniques—and allows these techniques to be modified in response to changing data and changing technology; and 4) provides authority over food “from the farm to the table.”

As pointed out in my testimony, there is also a need for an innovative, multidisciplinary team to undertake the changes in the current inspection system which the above legislation would permit. It is possible that these tasks could be handled by FSIS. However, this would represent a relatively radical departure from current practices, and, in the years since the 1985 National Academy of Sciences report, FSIS has not demonstrated that it is able to implement such changes.

This may be an instance in which it will be easier to start over than to attempt to make sweeping changes within an existing organizational structure. As one possibility, consideration should be given to establishment of an agency or Center which would have sole responsibility for food safety. Such a Center could combine inspection and regulatory authority of FSIS and FDA, together with the foodborne disease surveillance tasks currently conducted by CDC. While I realize that establishment of further bureaucracies is currently not in vogue, focusing of all food safety authority into a single group—which would also have the capabilities for monitoring outcomes (i.e., disease occurrence)—should be cost effective, particularly if the more onerous components of food inspection, such as carcass-by-carcass inspection, are eliminated.

Reference: In your testimony about poultry safety before another Senate committee in 1991, you mentioned the need for incentives to encourage producers to reduce levels of bacterial contamination.

Question 2: What kinds of incentives do you think would be most useful for the beef industry?

Response: In my testimony in 1991, I proposed (only partly in jest) that poultry plants be required to specify their average levels of contamination with *Salmonella* and *Campylobacter* on their product labels, thus allowing the consumer to compare products based not only on appearance but also on degree of bacterial contamination (and providing a strong incentive to poultry producers to reduce overall levels of contamination). The beef industry is a little different from the poultry industry in that contamination with pathogenic microorganisms is not as pervasive, making such an approach less workable. However, there clearly is still a need for monitoring for contamination with specific pathogens. Ideally, this would be a major component of Federal food safety inspection—with the incentive for improvement being the risk that the plant (and its products) would fail to pass inspection.

Reference: You have mentioned that it is unlikely that we will ever see meat that is 100 percent free of bacteria.

Question 3: In designing an improved meat safety system, how can we set standards for "acceptable" pathogen counts? What kind of research needs to be done to establish safe pathogen levels for humans? How long will this research take?

Response: Setting standards for levels of bacterial contamination is difficult. Realistically, it is also not possible with the scientific data currently available. The primary need is for epidemiologic studies which will allow specific levels of product contamination to be linked with disease occurrence. Studies to obtain these data have been outlined in each of the National Academy's reports on food safety. The necessary research could be conducted within a few years, with proper direction and financial support.

However, I would emphasize that this is not a "one time" process. There need to be ongoing studies, constantly reevaluating the impact of various food safety regulations—and modifying these regulations, as necessary, to minimize the risk of foodborne disease.

Reference: You have been a proponent of rapid on-line microbial testing for pathogens in meat.

Question 4: Specifically, what role do you see for microbial testing as part of a HACCP system?

Response: I think that on-line microbial testing should be an integral part of HACCP. If our goal is food safety, then it is essential that we monitor the variable (i.e., bacterial contamination) that has the primary impact on safety. Again, I do not see this as substituting carcass-by-carcass microbial testing for carcass-by-carcass visual inspection. What is being monitored is the overall process; if microbiologic indicators begin to rise during a production day, it would suggest that there was something wrong with the process, and (if levels were high enough) the plant should be shut down until appropriate corrections are made.

Reference: The presence of *E. coli* 0157:H7 has been reported not only in beef and raw cow's milk, but also in apple cider, municipal water systems, and foods such as non-dairy cheese, pea salad, and cantaloupe.

Question 5: Can all of these other reports of contamination be somehow linked to cattle? If not, what are the other sources of this strain of *E. coli*? Could there be other, non-bovine sources?

Response: We still do not completely understand the ecology of *E. coli* 0157:H7, and consequently it is difficult to say where or how it may be present in foods other than hamburger. The fact remains, however, that hamburger is a major source of the organism; efforts to reduce the incidence of disease must, of necessity, target hamburger and beef.

Question 6: As a physician and a public health expert, what is your opinion on the pathogen reduction technologies mentioned by Mr. Boyle, such as caracus sprays, vaccines, feed additives, electron beam treatment, light pulse treatment, genetically-engineered resistance, biological control, and, perhaps the most controversial, irradiation? Should Federal research efforts be directed toward these technologies? Are they safe for human health?

Response: I think that the approaches being taken by the industry to limit pathogens are commendable. However, I would hesitate for the Government to become too deeply involved in development of such techniques. The Federal role should be restricted to assuring food safety: the focus should be on an outcome, such as a documented low pathogen level, rather than on the technique used to assure that outcome.

At the same time, there is a need to assure that the technique used does not increase the risk of illness through another route: *i.e.*, bacteria may be killed, but the method by which they are killed may raise other dangers. My own feeling is that the outcome and the process used to get that outcome should be addressed separately. Producers would need to get approval from an appropriate Federal source (such as a food safety agency) for use of a specific technique (such as chlorine washes or biological control techniques), but then would be free to use whatever technique they wanted to assure compliance with regulations governing pathogen levels.

Dr. Edward Johnson

Question 1. What specific legislative changes do you believe are necessary to ensure the safest possible meat supply?

Response: NCA supports the total reevaluation of the Meat Inspection Act and the Poultry Inspection Act. Animal production practices, the types of products available, technology, a public health problem have all changed, but the industry and USDA is stuck with trying to make antiquated laws work in today's environment. NCA supports the development of *one* effective, equitable meat and poultry inspection act.

There also exists vast inequities between the rules and regulations governing meat inspection compared to that of poultry inspection. NCA encourages the subcommittee to seek a copy of the report prepared by the Research Triangle Institute titled; "Comparison of the USDA Meat and Poultry Regulation", that was recently completed at USDA's request.

Reference. USDA has indicated that they will implement a system of traceback in 1995 so they can identify and contain sources of contaminated meat.

Question 2. Is there any mandatory identification and traceback system that cattle producers would support? If so, please describe it briefly. Is there a way to simplify the system so it can be implemented this year instead of next year?

Response: NCA's 1990 study, an evaluation of the beef industry's trace back capabilities, which was presented to the subcommittee Members as part of NCA's testimony, concludes that fed and cull cattle which are directly marketed from producer to packer are virtually 99.9 percent traceable from the packer's cooler to the farm, ranch, or feed lot of origin. However, fed cattle marketed through livestock auctions have a traceability of less than 10 percent, mainly because there are no back-tag identification requirements for fed cattle. Cull cows and bulls (breeding cattle) marketed through livestock auctions have a traceability of 75 percent. The study showed that the primary identification used to coordinate the individual breeding animal with the original owner/seller, was the cardboard back tag applied at the auction barn prior to sale. This tag is applied as part of the rules and regulations of the *Brucellosis* Eradication Program, designed to assist the trace back of infected animals back to the herd of origin. No traceable cattle were found to have lost their back-tag prior to a slaughter. By law, meat inspectors are required to maintain the *Brucellosis* I.D. through inspection. The study showed the packers maintain the I.D. tag through the carcass chilling process. A highlight of the study found one auction market that routinely applied two *Brucellosis* I.D. tags (one on each hip) on each animal. Traceability of these animals was 100 percent. This simple practice shows that even if one of the back-tags is lost, animal I.D. is maintained through the use of the remaining tag.

NCA believes that this study shows that USDA could take 5 minutes and change the current rule that reads, auction markets must apply (one) *Brucellosis* tag, on breeding cattle, to read,—applied to *Brucellosis* I.D. tags (one on each side) on *all* cattle sold. The Department could then take five cents and buy the other cardboard back tag needed to improve the system. The other option is to take approximately

the next 5 years and five million dollars to debate, design, implement, and police an on-farm mandatory individual animal I.D. system for every farmer and rancher in the country.

Reference. Some groups have suggested that on-farm management practices to reduce pathogens should be mandated, if and when such practices are identified—

Question 3. Do you think on-farm mandates and regulation will be necessary? Can you suggest any effective alternatives to on-farm regulation that will still ensure that farmers will do what is necessary to reduce pathogens in their livestock?

Response: NCA's beef quality assurance program has established a national producer education network that has proven effective in eliminating chemical residues in beef. We have accomplished this through producers, veterinarians, extension service specialists, and Federal, state, and local authorities voluntarily working together, not through on-farm mandates and regulations.

The dairy industry is by far the most heavily regulated sector of the livestock industry, and yet chemical residues are still found in dairy-beef. However, to the dairymen's credit, the chemical residues in dairy beef have drastically declined over the last 3 or 4 years, again through the efforts of a voluntary quality assurance program.

If current and future research shows that farmers and ranchers can improve or apply management practices that reduce pathogens in live cattle, NCA stands ready to provide the information and technology to producers through the BQA program.

Awareness and education are the key. Instead of taking Federal dollars to develop and then police on-farm regulations, why not provide USDA adequate funding to work with producer organizations in creating the educational programs that provide the information and technology to help us improve preharvest food safety?

Reference. Your organization has expressed some concerns about the FSIS directive for mandatory trimming or "zero tolerance".

Question 4. Do you think this directive should be abandoned altogether? Why? If not, how should it be changed?

Response: NCA supports the Zero Tolerance Directive, no one wants physical contaminants in their food. NCA's problem with zero tolerance is the current inequitable interpretation of the rule that currently exist between inspectors from one region of the country to the other, and USDA's current rule, which has no scientific basis, that the best way of removing physical contaminants is by trimming with a knife. In fact, regardless of best intentions, there is no evidence that the Zero Tolerance Directive is accomplishing any pathogen reduction. The preliminary spray washing study, that was presented to the subcommittee members as part of NCA's testimony, shows that a combination of water temperature and pressure and the inclusion of a ozone or bactericide is effective at removing physical contaminants, and far superior to removing microbiological contaminants, than that of hand trimming. The industry's original intent for spray wash studies was to affect the further reduction of pathogens, not necessarily to replace hand trimming. NCA is hopeful, that when presented this data, USDA will readily accept and apply this technology to change and improve this inadequate directive. Pilot spray wash studies demonstrate an ability to significantly reduce microbiological levels on carcasses.

Reference. You have also expressed some concern about the order of the carcass wash and carcass trim processes.

Question 5. What do you see as the problem with the existing USDA guidelines? What do you think should be done?

Response: The existing guidelines state that physical contaminants should be removed by trimming. The washing versus trimming research project outlined in **Question 4**, shows that the additional handling of carcasses during the trimming process and the extended time the carcass is exposed to the warm moist air of the slaughter room, enhance pathogen cross contamination and growth.

USDA should expeditiously review the wash versus trim study, once it is presented to them, and if found satisfactory, immediately change the trim-only requirement to allow packing plants to implement the spray system.

SENATOR CRAIG'S QUESTIONS PRESENTED TO PATRICIA JENSEN WITH RESPONSES THERETO

Reference. In April 1992, Food Development section of the "Prepared Foods" magazine notes that:

"The notion of astronauts having to deal with food illness in space drove the U.S. Army Natick Laboratories—in conjunction with the Pillsbury Company—to apply HACCP first to foods produced for space missions. With an eye toward preventing food liability problems, Pillsbury then applied HACCP to foods consumed by earthbound consumers."

I understand you worked for Pillsbury in the past.

Question 1. Could you give us any insight into the development of this program (HACCP), report on its successes, and what plans the Department has regarding this process?

Response. The focus of a HACCP system is preventive in nature. It is intended to identify those points within a production system where potential hazards can occur and to eliminate, minimize, or reduce the hazard. You are correct in noting that Pillsbury was involved in the very earliest concepts of HACCP. The success of the system was first demonstrated in the absence of foodborne illness among this country's astronauts. Another notable success was with low-acid canned foods. The Food and Drug Administration published a rule in the 1970's concerning the proper controls on thermally processed canned products, after serious foodborne illnesses among these food products had occurred. The number of foodborne illnesses attributable to these food products dropped dramatically after the industry adopted these controls on food products. Similarly, in the 1980's, USDA published a rule on proper controls for the cooking and handling of roast beef products following several serious foodborne illnesses involving rare roast beef sold in delis. Again, the effectiveness of the cooking and temperature controls for roast beef can be assessed in the reduction of foodborne illness outbreaks attributable to this product. While neither of these earlier FDA and USDA rules mandated complete HACCP systems, each of these efforts demonstrates that when properly identified controls are introduced in food production systems the incidence of foodborne illness from targeted food products is reduced.

Secretary Espy has announced his intention to mandate the use of HACCP in meat and poultry establishments under Federal inspection. Prior to proposing a rule, the Secretary has charged FSIS with having a roundtable discussion with representatives from all constituent parties to frame and debate the issues that will form the context for the rule when it is proposed. The HACCP Round Table will be held will be held on March 30–31, 1994, here in Washington, DC. at the Hyatt Regency on Capitol Hill. The Round Table sessions are scheduled for 8:30 a.m. to 5:30 p.m. All Members of the Subcommittee are invited to attend as are staff members. Following the roundtable session, the Secretary will charge FSIS with drafting the proposed mandatory HACCP rule. It is anticipated that the rule will be ready for publication in about 6 months.

Reference. During the hearing last year, Secretary Espy indicated that, in the short term, one of the plans to address the situation would be encouraging the use of organic sprays to reduce bacteria on the surface of beef carcasses.

Question 2. Can you give the status of the use of organic sprays?

Response. In November 1993 the Food Safety and Inspection Service (FSIS) issued a Directive that provided instructions to FSIS personnel on monitoring of preevisceration organic acid spray systems for livestock carcasses. A Directive covering the use of antimicrobial systems during slaughter and dressing of livestock and poultry has been drafted. Also, a regulation to add lactic, acetic, and citric acids as antimicrobial agents is being drafted by FSIS.

Currently over 20 establishments slaughtering livestock under Federal inspection have approval to use organic acid spray systems. Most of these systems (15) are postevisceration spray systems. The others are preevisceration spray systems. FSIS continues to receive and review requests from establishments to use acid spray systems.

Reference. Secretary Espy indicated in the hearing last year that there were short-term as well as long-term actions that were being initiated to improve the inspection system.

Question 3. What is the status of these initiatives?

Response. Charts providing the status of over 70 pathogen reduction activities being undertaken by the Food Safety and Inspection Service and the Animal and Plant Health Inspection Service are enclosed.

Reference. The USDA has already approved irradiation for poultry and fruit and vegetables. Secretary Espy indicated last year at the hearing the department was looking at a proposal to go forward with a petition for irradiation with beef.

Question 4. What is the status of that proposal? Does the Department have a target date for making this decision?

Response. Preparation of a petition to the Food and Drug Administration (FDA) to amend their regulations to permit the irradiation of red meats (beef, veal, pork, lamb, and mutton) for the same purposes and under the same conditions as those already permitted for poultry is being prepared in the private sector. Secretary Espy has written a letter to Secretary Shalala encouraging timely evaluation of the petition. USDA will provide results of research studies as well as scientific support to the petitioner. The Department is not in a position to proscribe target dates for submission, however, we expect that the petition will be submitted by mid-1994.

Reference. In the second quarter, 1992 edition of *Choices* magazine it indicted, in referring to USDA review of HACCP, that:

"HACCP will be tested in volunteer plants for about a year, after which another USDA team will evaluate the results. If successful, HACCP is to be gradually incorporated into meat and poultry safety regulations."

Question 5. Is that a true characterization of the USDA review process for HACCP? Where is USDA in the process of implementing HACCP?

Response. In 1990, FSIS initiated a series of activities that would provide the Agency with information concerning Hazard Analysis and Critical Points (HACCP) Systems in meat and poultry plants.

These HACCP activities consisted of:

- (1) consultations and public hearings, with views solicited from FSIS employees, professional organizations, consumer and other public interest groups, and industry;
- (2) workshops, conducted by a "Special Team" of experienced FSIS personnel, for the development of model or generic and plant-specific HACCP plans for selected product classes (refrigerated foods, cooked sausages, poultry slaughter, swine slaughter and ground beef);
- (3) three-phase in-plant testing, consisting of trial implementation of the plant-specific HACCP plans; and
- (4) evaluations of the HACCP models and implementation process at the pilot plants from a case studies approach.

Because of time and resource constraints the implementation phase of testing the models were limited to the refrigerated foods, cooked sausage, and poultry slaughter models. The Agency was able to obtain three volunteer plants for each of the three models.

The "implementation" of the plant-specific HACCP plans (model testing phase) consisted of three phases (baseline, implementation, and operational phases). The refrigerated foods pilot was started June 1991 with on-site awareness training at the first plant and operational phase ending April 1993. The cooked sausage pilot started May 1992 and ended June 1993. Lastly, the poultry slaughter pilot started May 1993 and ended late August 1993.

Presently, the Agency is analyzing the results of the myriad case study activities including quantitative and qualitative analyses (e.g., microbiological and chemical testing, and personal interviews with plant and inspection personnel) writing a report of the case studies.

In May of 1993, Secretary Espy requested FSIS to present him with a plan for making HACCP system of process control mandatory in all the Nation's Federally inspected meat and poultry establishments.

As mentioned previously, at the Secretary's direction to ensure greater input from all constituent and other interests, FSIS is providing all constituent groups with a forum to comment on development of a mandatory HACCP system.

Formal membership of the roundtable includes constituents from:

- Meat and Poultry Industry and their Representatives (Including Grocers and Retailers)
- Consumers and their Representatives
- Scientists and Professional Scientific Organizations

- Producers and Farmers
- FSIS Employees and their Representatives
- Federal, state, and local governments
- Public Health Officials and Medical Doctors

The Round Table will assist the Agency in developing a proposed rule for HACCP in the Nation's Federally inspected meat and poultry establishments. The development of the proposal will be carried out as dictated by the Administrative Procedures Act, the Regulatory Flexibility Act of 1988, and Executive Order 12866 Regulatory Planning and Review.

Reference. The October, 1993 edition of *Government Executive* magazine states:

"The food inspectors union—the National Joint Council of Inspection Locals—is seen by many meat producers as a recalcitrant defender of the *status quo*. The union, producers say, has opposed efforts to move beyond visual, carcass-by-carcass inspections because some of its members—many of whom have only high school educations—would lose their jobs.

Union officials say their concerns go beyond job security. David Carney, who handles legislative liaison for the inspectors, contends that the vast majority of inspectors have never been given any retraining or continuing education."

This is not a new allegation. The Unions and USDA may both be responsible.

Question 6. Do you agree with these statements?

Reference. You have hired more inspectors this year and the president's budget proposes hiring an additional 200 inspectors. During the subcommittee hearing last year, Dr. Cross indicated that the training for the new inspectors would go beyond that of the past or in his words "move away from the organoleptic inspection system . . .

Question 7. What has been done to adjust the training and work processes of the inspectors within FSIS?

Response (Questions 6 and 7). FSIS believes that the current inspection workforce needs further training to fulfill its regulatory responsibility, and is currently being trained on the rapid changes brought about by the advanced technology in the food industry.

During the past 10 years, rapid advances in technology have prompted a dramatic increase in its impact on FSIS training needs. The demand to train new employees and retrain experienced employees has increased dramatically. We have adjusted to the demand by increasing On-The-Job Training (OJT) for all Food Inspectors. We have found that this type of training has been very effective and cost efficient in updating inspectors who have been on-the-job for a number of years and implementing new changes. Some of the OJT given in Fiscal year 1994 was: Pre-op Sanitation; Wellness; Clean Meat Program; Progress Enforcement Action, and Performance Based Inspection System (PBIS) Staffing. These programs have been done either on-the-job or in a location near the job site. OJT is a continuing supervisors function used when reviewing changes in regulations, directives and notices with field inspectors. Each employee is encouraged to further their careers and take the opportunity to enroll into any of the many training programs that are available.

For example, opportunities for all GS-5/12 employees interested in upgrading skills the Agency provides training programs such as the Career Development Academy and the Frontline Leadership Curriculum. Self-Study Courses are available for all employees in Math, English, Science, *e.g.*, Animal, Meat, Foodborne, Food Ecology, etc., Sanitation, Canning Technology and others. From 1977 to present, 9,200 employees have completed Self-Study Programs. From October 1993 to present, 975 courses have been completed.

An Audiovisual Lending Library is available to all employees in FSIS. Subject matter of materials in the collection include; Animal Science, Computers, EEO/Civil Rights, Foodborne Disease, Food Science/Food Technology, Health/Safety, Mathematics, Meat/Poultry Inspection, Pathology, Sanitation and others. During Fiscal year 1993, 1,407 employees have requested and received audiovisual programs for viewing.

FSIS realizes the need to have all employees retrained to keep up to date on the latest technology. We also know that it is important to get the best training available staying within our budget. We have found On to be an effective means for training employees on new or revised inspection procedures.

All new inspectors hired for livestock or poultry slaughter receive a 12-day course designed to cover subjects that relate to the Federal Meat and Poultry Inspection Acts. Areas covered include: safety; sanitation; humane slaughter; antemortem and

postmortem inspection procedures; viscera separation; control of restricted products; control of condemned and inedible products; coolers; shipping and receiving; labeling and marking; reinspection; microbiology (including foodborne illnesses); fabricating and portion control; quality control concepts; Hazard Analysis and Critical Control Point Systems; stress management; meat industry practices; inspector/plant management relations; and others. Written examinations and exercises are used to evaluate the trainees' acquired skills and knowledge. This training continues when the trainee returns to their permanent duty station.

From 1990 to the present, 1,592 new inspectors have received formal livestock and poultry training at Texas A&M, at a cost of \$1.6 million. This cost estimate doesn't include the money incurred while filling in behind the employee being trained.

FSIS believes that we are doing a good job at training new inspectors and retraining are older employees for the current inspection program.

Currently the Agency's Human Resource Development Division (HRDD) is conducting an Evaluation Study of all the programs being given at the training center. At the present, FSIS is making the transition from an organoleptic inspection system and putting more emphasis on microbial inspection. New programs are being developed to address new standards.

Reference. The October 1993 edition of *Government Executive* magazine states:

"For all its successes, the current inspection system is flawed by its inability to detect deadly microbes invisible to the eye."

Question 8. Do you agree with this statement? What are you doing to correct that within available science?

Response. Many of the new inspection procedures and regulations of the FSIS have been developed because of the inability of the human eye to detect microorganisms. The regulations have been designed to require plants to use procedures that have been shown through use and time to control the environmental conditions that may lead to contamination of meat and poultry with pathogens or the times and temperatures that may allow pathogens present the opportunity to multiply to levels where human illness may result. Likewise, inspection procedures should be designed to recognize these environmental conditions and verify that plants adequately control them. This approach is the basis of the Hazard Analysis Critical Control Point (HACCP) system that is recognized as the one system in use to date that can control the involvement of food products in human illness. HACCP does not concentrate at controlling foodborne illness at only one point in the food chain.

Secretary Espy recognizes that in-plant testing would represent a breakthrough in our ability to further protect the public health and he has the Department pursuing the development of rapid tests on several fronts. Agricultural Research Service (ARS) scientists have determined that a commercial bacterial test can be adapted to confirm high levels of microbial contamination on meat carcasses. FSIS and ARS are evaluating the test and striving to reduce the time it takes to perform the test which now is about 50 minutes.

FSIS has initiated a project to examine incorporating microbiological sampling of equipment in FSIS preoperational sanitation inspection. A pretrial pilot was conducted at 10 plants from November 1993 to February 1994. Four commercially available test kits designed to detect indicator organisms were tested. Information from this pilot is being evaluated in preparation for expanding the project this spring. The project will determine the adaptability of the tests to the environment of meat and poultry plants, the effectiveness of the tests in detecting the presence of indicator organisms, and the effectiveness of plants' sanitation and cleaning systems.

Integrating microbiological testing into inspection at the slaughter production phase is being studied by FSIS. Inspectors collect swab samples from livestock and poultry carcasses and forward the samples for laboratory analyses. Results are correlated with procedures carried out by the plant to remove visible fecal, ingesta, or milk contamination from livestock and poultry carcasses.

Many foodborne pathogens are zoonotic in nature meaning simply that they are carried into the slaughter establishments on the hide or feathers of animals or in their intestinal tract. Control of slaughter procedures can minimize the occurrence of these pathogens on final product, but it can never completely eliminate it. Controlling the presence of these organisms in the live animals on the farm can lead to significant reductions in their involvement in human foodborne illness. In 1981, FSIS proposed to the Agriculture Research Service that it begin to conduct research that can lead to reductions in the incidence of *Salmonella* in domestic animals. In 1983, this request was extended to control of *Campylobacter*, and in 1987, *E. coli* O157:H7. The research has been slow, but is now beginning to show some success.

Research is also being conducted to find slaughter and dressing procedures that are able to better remove the pathogens expected to still be present on animals presented for slaughter. Hazard analyses of slaughter operations have been conducted for many years to identify locations in the process where added control is both possible and where it is likely to have the most benefit in terms of controlling bacterial contamination and multiplication. During the mid-70's, several outbreaks of human *salmonellosis* epidemiologically associated with cooked beef and roast beef were traced to commercial establishments that produced these products. The USDA responded to the threat to human health by promulgating an emergency regulation that established a minimum cooking temperature. Following an industry funded heat lethality study using a protocol defined by the Microbiology Division, FSIS, the regulation was revised. The revision provides a combination of alternative times and temperatures, equivalent to a seven log reduction (7D) of *salmonellae*, that could be used to produce a safe rare roast beef product. A comprehensive regulation that encompasses all phases of cooked beef production (cooking, cooling, cross-contamination and sanitation) was instituted in 1983. This regulation addresses the need to control the presence of *salmonellae* in cooked beef products. Thorough review and analysis of the epidemiologic data, and the elucidation of risk factors has enhanced understanding of effective preventive measures. These measures, when adhered to in all respects, provide assurance to the consumer of a safe and wholesome product, and enables FSIS to fulfill its regulatory mandate.

The FSIS actions, including the regulation (9 CFR 318.17) and the statistically designed monitoring program initiated in July 1983 to track compliance, have been recognized by investigators at the Centers for Disease Control (CDC) as effective in reducing consumer risk from *salmonellosis*.

In 1988, FSIS contracted with the same private laboratory to repeat the heat lethality study for *Listeria monocytogenes* and *Escherichia coli* 0157:H7. Based on the results of the study, FSIS is reasonably confident that the regulatory cooking requirements for cooked beef will not need to be increased to provide safety from either of these two organisms.

Recently, FSIS proposed regulations that extend the concepts of control introduced in the cooked beef regulations to other products under FSIS jurisdiction.

In addition, FSIS conducts routine laboratory testing programs for other ready-to-eat meat and poultry products to verify that industry procedures for the manufacture of these products are sufficient to eliminate the presence of *Salmonella* and *Listeria monocytogenes* pathogens.

The success of the cooking regulations in reducing the occurrence of *salmonellosis* has caused these temperatures to be incorporated in the requirements of the regulations of several states and the FDA Food Code. Recently, the Food Code drafters at FDA adopted cooking temperatures for the safe production of cooked patties that are based on the research funded by FSIS and the recently published FSIS Cooked Patty regulations.

The final preparation of meat and poultry products is critical to reduction of human foodborne illness. The Centers for Disease Control and Prevention have indicated in its analysis of foodborne disease from 1973-1987 that temperature abuse and undercooking are the factors most often responsible for the hazard condition. For this reason, and based on the requirements for production of processed product under Federal inspection, the FSIS Meat and Poultry Hotline has been providing 800 service advice to consumers for many years.

The goal FSIS has been, and will continue to be, guided by is to use science to make progress on the reduction of human foodborne illness. The principles of the HACCP system provide a scientific basis toward this goal. The specific ways in which the FSIS will be upgrading the science base of inspection have been outlined in the Pathogen Reduction Plan.

POSITION STATEMENTS

THE AMERICAN FARM BUREAU FEDERATION

The American Farm Bureau Federation (AFBF) thanks Senator Daschle and Members of the Agriculture Research, Conservation, Forestry and General Legislation Subcommittee for holding a hearing on meat, poultry and seafood inspection.

AFBF shares the commitment of this subcommittee and of the U.S. Department of Agriculture (USDA) to a science-based inspection system for meat, poultry and seafood which adequately safeguards human health and promotes the highest levels of consumer knowledge and confidence.

The recent outbreak of illness, resulting from the presence of the *E. coli* 0157:H7 bacterium and the accompanying ineffective handling and cooking of a ground meat product, highlighted the need for improvements in meat inspection, and meat preparation. We believe a commitment exists both within the industry, as well as within USDA, to make the necessary improvements in the inspection system and the information delivery system.

In fact, this process of improvement has begun. As we move forward, we must be clear as to the effectiveness of our current systems, the impediments to meaningful change, the need for science-based decisionmaking and the importance of a realistic timeframe.

There is no way to adequately measure the individual impacts of the tragic events of last year. In shaping effective public policy, we are asked to look at those events in the context of the effectiveness, and safety of the livestock, and meat production processing, and distribution system in total. The meat inspection system is not hopelessly broken. It is in need of repair. Repair may involve some revolutionary changes as Secretary Espy has described, but these revolutionary changes can take place on an evolutionary timetable without subjecting the public to undue risk. Our current meat inspection system will more than adequately protect us as we move forward.

USDA, Members of Congress, and industry representatives must convey to all consumers both their commitment to improvement and their faith in our current activities. These messages are in no way inconsistent.

Members of the meat and poultry production and processing industries have long supported implementation of the Hazard Analysis Critical Control Point (HACCP) system. We hope that HACCP will continue to be the guiding framework for changes in meat and poultry inspection. HACCP focuses control and monitoring of potential contaminants on all the key areas of production and processing. It analyzes risk throughout the system and allows for continued improvements all along the line, rather than focusing only on evaluating individual carcasses. A HACCP approach will also clearly identify risks and the procedures necessary to reduce those risks for meat and poultry products once they are in the home of the consumer or being prepared in a commercial establishment. No food safety program will be successful without that final component.

Farm Bureau believes that the "farm to fork" implementation of a HACCP based system is appropriate. We must be sure that any required changes are science based and make sense from the cost benefit point of view. Changes in farm level production practices may be costly and difficult to implement. If farmers and ranchers are to bear the costs of those changes, there must be a verifiable improvement in the safety of meat and poultry products at the consumer's table.

Microbiological testing can be an important component of HACCP evaluation and monitoring. Microbiological testing is an evaluation tool not a bright-line standard. Microbiological standards are inappropriate and not workable from a policy point of view.

Farm Bureau believes that USDA should continue to strengthen and expand its overall role in food safety. USDA has a tremendous expertise in food safety and has a delivery mechanism capable of reaching all the participants in the "farm to fork" spectrum. Establishing an undersecretary for food safety as a part of USDA reorganization would be a positive step to elevate the food safety role of USDA. USDA must continue to demonstrate a long-term commitment to food safety.

Although not directly a focus of this hearing, seafood inspection continues to be a concern of Farm Bureau and of the Senate Agriculture Committee. A majority of U.S. seafood is imported, and a growing percentage of domestic consumption is a product of aquaculture. USDA has the infrastructure and expertise to play an important role in inspection of foreign seafood plants and product and domestic aquacultural products. USDA should aggressively begin activities in the areas of seafood inspection that current statute allows.

Assuring supplies of safe and wholesome meat, poultry and seafood must continue to be the goal of the Federal meat inspection programs. Our efforts as industry and as government to ensure that the meat inspection process is always improving must be continuous.

THE AMERICAN VETERINARY MEDICAL ASSOCIATION

The American Veterinary Medical Association, on behalf of its 54,500 members, is pleased to contribute to the hearing record on the issue of meat safety.

Veterinarians traditionally have a vital role in the advancement and maintenance of food safety for the benefit of society. Veterinary medicine has a several hundred

year history of contributions and is the only health profession that is involved in the full spectrum of food safety from farm production to consumption. Veterinarians seek to improve both animal and human health. In fact, AVMA has adopted food safety as one of the top goals of its strategic plan. That plan supports the organization's objective: . . . to advance the science and art of veterinary medicine, including its relationship to *public health*, biological science, and agriculture." (Emphasis added).

It is the policy of the American Veterinary Medical Association to help assure that the supply of foods of animal origin is wholesome and free of harmful chemical, parasitic, microbiological, or pharmaceutical contaminants. The association encourages its members to promote responsible animal production and husbandry to increase the safety and quality of animal-origin food. We actively pursue appropriate educational, legislative, and regulatory measures to meet those goals.

We support legislation to create a coordinated, integrated, unified food safety regulatory program that is managed by a single Federal agency that cooperates closely with state and municipal programs. We believe the single agency should be located in the U.S. Department of Agriculture which has the expertise and resources to manage the full scope of the food quality assurance program as a continuous process from breeding through production, processing, distribution, sales, and consumption, including consumer education through the cooperative extension service and other forms of outreach.

We support the legislation proposed by the Chairman, Senator Daschle, which would make the Food Safety and Inspection Service an independent agency within the Department of Agriculture. Creation of an agency with the sole mission of food safety is a major, progressive action towards improvement of meat safety. We encourage further action to harmonize regulation of other foods based on risk assessment.

AVMA promotes assurance of food quality and safety, including the production of safe and wholesome food from healthy animals that are raised in a healthful environment, with close professional monitoring to prevent traumatic, infectious, and parasitic diseases and chemical residues. We support quality assurance programs as cooperative efforts between food animal producers, and their veterinarians, to meet or exceed standards established by government regulators, and expected by consumers. Mandatory permanent individual animal identification is necessary to enable tracking of animals through marketing channels to final products, and traceback to origins.

AVMA advocates a science-based food inspection system as a comprehensive process of ante- and postmortem evaluation, which includes detection of physical defects, infectious agents, pharmaceuticals and chemical residues in food. The system should include Hazard Analysis Critical Control Point (HACCP)-based risk analysis. Careful organoleptic examination of all carcasses should be one of the critical control points of a HACCP system for the slaughter process. Control of raw materials is an inherent part of any HACCP program. Visual and physical examination is the most efficient and effective method to exclude unsafe or unwholesome products caused by tumors and other neoplasms, systemic infectious diseases, parasites, abscesses, and inflammation. Microbiological monitoring of facilities and products at slaughter, processing, distribution, preparation, and sales should also be part of the comprehensive food safety process. We encourage research on technological and personnel approaches to improve food safety. Before present procedures are modified or eliminated, scientific assessment must ensure that food safety will not be adversely affected and will actually be improved.

The AVMA is committed to working with legislators, Federal and state regulatory agencies, consumer groups, and producers to define and implement a comprehensive, coordinated, and effective food safety program. We urge steady progress towards a system based on science.

Thank you for the opportunity to comment on a subject of vital interest to the veterinary profession, American agriculture, and the U.S. consumer.

FOOD AND DRUG ADMINISTRATION, PUBLIC HEALTH SERVICE, DEPARTMENT OF HEALTH AND HUMAN SERVICES

The Food and Drug Administration (FDA) is pleased to have the opportunity to update the subcommittee on our actions following the January, 1993 outbreak of *hemorrhagic colitis* caused by *Escherichia coli* 0157:H7 from undercooked hamburger. As you know, FDA is a component of the Public Health Service (PHS) in the Department of Health and Human Services (DHHS). In brief, the FDA has been active in protecting consumers from *E. coli* 0157:H7, utilizing our regulatory

authority, conducting research and cooperating with the United States Department of Agriculture (USDA).

Of primary importance in helping the state and local governments prevent foodborne disease:

On January 21, 1994, Secretary Shalala and Commissioner Kessler announced FDA's updated model Food Code. Major revisions were made to this document to incorporate the principles of mandatory safety controls for food handling at the retail level. These revisions were based on the Hazard Analysis Critical Control Point (HACCP) approach to provide reinforcing preventive controls at the retail level to protect the public from foodborne disease.

The Agency also:

- consulted with FDA-regulated industry on some of the products that are potentially susceptible to contamination by *E. coli* 0157:H7;
- issued an alert on *E. coli* 0157:H7 to all physicians and health care workers;
- developed several scientific techniques and continued research to identify and control the organism;
- conducted training for Federal inspectors of nursing homes on control of this organism;
- updated and distributed a video tape training tool for nursing home food service personnel, and;
- published a special article in the January/February edition of the *FDA Consumer* magazine.

Jointly with USDA, we:

- conducted a video teleconference with state and local regulatory officials on controlling *E. coli* 0157:H7;
- developed, with the meat industry, two brochures on prevention of *E. coli* disease, one for consumers and one for food service personnel.

Before providing detail on these activities of the past year, we would like to present some background information on the control of foodborne illness.

BACKGROUND

Foodborne illness is a major cause of morbidity in the United States and results in an estimated 10,000 preventable deaths per year. FDA experts have estimated that each year, 24–81 million people become ill from microorganisms and their toxins in food. For most people, foodborne illness is minor and may result in a lost day from work. For others, however, especially the very young, the elderly, and those who have chronic illnesses or impaired immune systems, foodborne illnesses are more serious and may be life threatening. Foodborne illnesses are also costly to society in terms of lost earnings and medical expenses, with published estimates ranging from \$7.7 to \$23 billion, not including lost productivity.

In the late 1980's, the Public Health Service convened a consortium of national health experts and organizations to develop a national strategy for improving the health of the Nation over the coming decade. The cornerstone of this effort was the development of a set of national health promotion and disease prevention objectives for the year 2000. Twenty-one objectives were identified, one of which is to reduce foodborne disease caused by *Salmonella*, *Campylobacter jejuni*, *E. coli* 0157:H7 and *Listeria monocytogenes*, four of the most important foodborne pathogens in the United States based on the number of reported cases that occur and their severity. These objectives were issued in a report entitled *Healthy People 2000*, and all the organizations that helped develop the report agreed to work together toward achievement of the objectives. FDA's Center for Food Safety and Applied Nutrition has the lead responsibility for working with other public and private sector organizations for achieving the food safety objectives.

Infections by *Salmonella* and *E. coli* 0157:H7 are actually increasing in incidence, and decreasing their occurrence will be difficult. The growing proportion of our population that is compromised by immunologic deficiencies and age also exacerbates the problem.

Regarding risks at the retail level, because of our finite resources, FDA generally does not itself inspect restaurants, but relies on cooperative arrangements with the States. FDA's Retail Food Protection Program is the cooperative Federal-State effort that covers the food service, food vending and food store industries. At the subcommittee's hearing of last February, Douglas Archer, Ph.D., then Deputy Director for Programs, Center for Food Safety and Applied Nutrition (CFSAN), described FDA's role in assisting the States in the regulation of restaurant food. He

focused on the temperature guidelines for cooking of potentially hazardous foods, such as hamburger.

FDA assists and supports state and local regulatory agencies by developing uniform standards (known as model codes), providing technical assistance and interpretation, producing training aids, and offering training programs and evaluation of state programs. The major causes of foodborne illness that we address fall into three broad areas: (1) personnel, (e.g., transfer of organisms from ill employees); (2) food (e.g., insufficient cooking and holding temperatures), and; (3) equipment and facilities (e.g., improper cleaning and sanitization of food contact surfaces). The model codes provide recommended standards that we encourage state governments to adopt.

Cooking time, cooking temperature and the bacterial load in the food are factors that must be considered in establishing cooking directions for potentially hazardous foods. On January 28, 1993, in response to the outbreak, FDA provided interim guidance to Federal, state, and local officials recommending that ground beef products should be cooked to heat all parts of the food to at least 155 degrees Fahrenheit in order to provide an added margin of safety.

In addition to regulatory efforts by government, consumers can also take steps to avoid foodborne disease. Over the past few decades, educational materials designed to increase consumer awareness of methods to prevent foodborne disease have been developed and distributed by public and private organizations at the national, state, and local levels. However, investigations of foodborne disease incidents have repeatedly shown that many consumers do not understand the hazards or do not take precautions to reduce their risks.

RECENT ACTIONS

We would like to update you on our actions of the past year. A year ago, our attention was focused on understanding the causes of the outbreak, researching the characteristics of the organism, and determining its susceptibility to various lethal processing steps. As you know, effective control measures must be taken in the context of the total production and distribution system. Cooking times and temperatures are only part of the picture. Ideally, pathogens such as *E. coli* 0157:H7 would not be present in food but, because this is not yet an achievable goal, their numbers should be kept as low as possible.

Joining with the Centers for Disease Control and Prevention (CDC), our sister agency in DHHS, we pledged to cooperate with USDA, as it seeks to reduce potentially dangerous microorganisms in raw meat products. Our efforts complement each other since FDA is also working to reduce the level of such microorganisms in the raw foods that we regulate. A series of interagency meetings aimed at bringing FDA and USDA cooking temperature recommendations in line culminated with an August 2 letter from FSIS Administrator, H. Russell Cross, to CFSAN Director, Fred R. Shank, listing the agreed-to temperatures. These temperature recommendations are the basis for USDA's in-plant regulations on precooked meat patties and FDA's ground meat cooking recommendations in the Food Code.

THE FOOD CODE

Last month, DHHS announced publication of the 1993 edition of the Food Code. Interagency meetings, epidemiological information, and laboratory research all were vital in development of the recommendations in the Food Code. Provisions of the new Food Code are compatible with the Hazard Analysis Critical Control Point (HACCP) concept and terminology. HACCP is a system of ensuring food safety that involves identifying and monitoring the critical points in food preparation where the risks of foodborne hazards (microbial, chemical and physical) are greatest. Since the 1970's, FDA has mandated HACCP in the canned food industry; we recently proposed mandatory HACCP requirements for seafood processing and are also discussing making HACCP the basis for our general food safety regulations.

Other important revisions to the Food Code that protect consumers from *E. coli* 0157:H7 are:

(a) Restricting or excluding food employees who have been diagnosed or have symptoms of any of the four infectious diseases which are highly transmittable via food, including illness caused by *E. coli* 0157:H7.

(b) Prohibiting employees from contacting exposed, ready-to-eat food with their bare hands, and requiring use of suitable utensils such as tongs, deli-tissue or gloves.

(c) Requiring that information be provided on the risks to certain vulnerable consumer populations about eating raw or undercooked foods of animal origin. Such information can be provided through brochures, placards or menu labels.

For a strategy to prevent a reoccurrence of the tragedy caused by the *E. coli* organism to be comprehensive, it must be all encompassing—going from farm to table. It must address all points in the food chain where pathogens can be effectively controlled or eliminated. The FDA/USDA strategy for reducing foodborne disease does go from farm to table, emphasizing additional targeted surveillance and enforcement supported by research, and educational programs to alert consumers and food service workers about the hazards naturally associated with raw foods and with unsafe food handling practices.

RESEARCH EFFORTS

FDA routinely conducts research in support of its regulatory mandate and has intensified research efforts on *E. coli* 0157:H7 since last year's outbreak. This past year, we conducted survivability studies of this microbe in foods regulated by both FDA and USDA. We also developed DNA fingerprinting methodologies to identify rapidly the source of the organism, and we developed rapid methods to identify infected animals in a herd.

At least two outbreaks of *hemorrhagic colitis* caused by *E. coli* 0157:H7 have been epidemiologically linked to products regulated by FDA, apple cider and mayonnaise-based salad dressings. Until now, the acid nature of these products has proven to be an effective antimicrobial. Though *E. coli* 0157:H7 has never been isolated from these products, recent research has demonstrated that it can survive in apple cider for 20 days and in mayonnaise for 40 days, when both are kept at refrigerator temperatures. The ramifications of this unusual survivability, coupled with the low infectious dose associated with this microbe, have been communicated to the industries involved so they can consider the need for control measures.

FDA has performed additional research to determine the minimum time/temperature requirements necessary to adequately destroy this microbe in ground meat. These time/temperature requirements have been incorporated into the newly released Food Code.

FDA has been cooperating closely with USDA on developing HACCP principles and identifying Critical Control Points for meat products both through the National Advisory Committee on Microbiological Criteria for Foods (NACMCF) and by serving as a voting member on USDA's Track I and II Technical Assistance Group selection committee. FDA was actively solicited and has commented on USDA's Pathogen Reduction Plan, which is intended to reduce microbial pathogens in meat products through the use of currently available methodology. In support of this plan, FDA has developed three rapid tests for the identification of *E. coli* 0157:H7, two of which employ the technology of Polymerase Chain Reaction (PCR). These methods still require an enrichment step to increase the numbers of *E. coli* found in ground meat products, thus making these methods appropriate for laboratory use, rather than field use. However, they do significantly reduce the time required to confirm the presence of this organism from several days to less than 1 day. Research continues in this area, because low numbers of this bacteria are capable of causing human illness upon ingestion (low human infectious dose), and current technology does not allow rapid detection of these levels.

In addition, FDA is collaborating with USDA scientific staff located in Ames, Iowa, to develop rapid techniques to study the ecology of *E. coli* 0157:H7 and verify the effectiveness of disinfectants in removing this microbe from the animal stall environment.

FDA laboratories located along waterways have initiated studies to determine the survivability of this microbe in aquatic environments which may receive animal fecal matter from runoff following increased rainfall. This type of situation occurred in Milwaukee, Wisconsin, last year, resulting in cases of gastroenteritis due to the animal-carried parasite, *Cryptosporidium parvum*. Our research is to determine if estuarine waters or aquaculture ponds subjected to a large inoculum of *E. coli* 0157:H7 present in animal manure could cause contamination of fishery products.

EDUCATION ACTIVITIES

The Pathogen Reduction Plan, Healthy People 2000, and other initiatives to reduce foodborne disease, all emphasize the importance of education and training of consumers and food service workers. Over the last year, in response to the outbreak, FDA and USDA convened work groups to reassess how best to carry out our foodborne disease education and communications activities.

Despite widespread distribution of education materials on prevention of foodborne diseases, investigations of foodborne disease outbreaks have repeatedly shown that many consumers and food service workers still do not understand the hazards, or take precautions to reduce the risk. Providing education to food service workers is especially difficult because of the large number of people involved, high rates of employee turnover, language and literacy barriers, and nonuniform systems among States for training workers.

The FDA/USDA Education and Communication Campaign to Reduce Foodborne Disease intends to increase our effectiveness in reaching consumers and food service workers to take all necessary steps to prevent foodborne illness. This program consists of five components:

Information Exchange and Partnership Building. It is difficult for FDA and USDA to inform adequately all food service workers and the general American public about the best ways to prevent foodborne disease. For that reason, the agencies intend to increase their efforts to work with other public and private sector organizations to ensure that information on proper food handling practices are widely communicated. For example, FDA/USDA have worked successfully with the Food Marketing Institute over the past several years to convey food handling advice to retail food store employees. To encourage additional joint efforts, FDA/USDA conduct quarterly meetings of the Nutrition and Food Safety Education Task Force. This body consists of representatives from trade, professional and consumer organizations.

To facilitate the exchange of information between the numerous organizations that provide education on food handling practices, FDA has for years, through its State Training Lending Library, provided state and local officials access to training materials on foodborne disease. To augment this effort, FDA/USDA are establishing a Foodborne Illness Education Information Center. The Center is designed to encourage the exchange of information about education and training programs directed at food service workers and the public and to make it easier for organizations to find partners for future education programs. The Information Center will be housed in the Food and Nutrition Information Center of USDA's National Agricultural Library. The Center will maintain a database of education activities and materials on foodborne disease, operate an electronic bulletin board on foodborne disease education, answer inquiries, and refer callers to organization and foodborne disease experts.

FDA/USDA also plan to increase the dialogue with the thousands of state and local health and regulatory agencies. Because of the large number of agencies to contact, we will utilize multiple communication channels. For example, a video teleconference was conducted on September 2, 1993, for state and local officials to interact directly with FDA and USDA experts. The FDA PRIME CONNECTION Electronic Bulletin Board, established in 1992 for state and local officials, is being expanded to include information from USDA. USDA's proposed Safe Food Handling Labeling regulation was disseminated using this bulletin board.

Survey Research and Evaluation Activities. Over the past several years, FDA/USDA have conducted consumer surveys that provide additional insights on how best to educate consumers to prevent foodborne disease. FDA/USDA are analyzing a 1993 survey dedicated entirely to food safety issues. Topics included food safety risk perception, reported eating practices, awareness and knowledge of certain microorganisms, reported food handling practices, and reported foodborne illness experiences. Many of the food handling and food safety questions from the 1988 Health and Diet Survey were repeated in the 1993 study so that trends can be examined. A comprehensive literature review of other studies relating to foodborne disease will complement this survey information.

Education Messages for the Media. The press has always been extremely interested in foodborne disease, and more so since the *E. coli* 0157:H7 outbreak of January 1993. We hope to maximize the educational value of the current high level of press coverage. The goal is to assure that the press has sufficient resource material to explain the hazards of foodborne disease and how proper food handling practices can prevent or minimize these hazards.

FDA/USDA will direct their communications materials to the trade and professional media as well as the public media. For example, FDA/USDA will continue to: (a) provide regular updates to the public, trade and professional press on recent foodborne disease outbreaks and research studies; (b) prepare newspaper columns and video news releases on how consumers can prevent foodborne disease; (c) provide media interviews and feature segments on widely viewed programs.

Education Materials for Consumers and Priority Audiences. For years, FDA/USDA have developed and widely distributed brochures, articles and reprints on

foodborne disease. During the last year, we continued to emphasize programs for people who are at increased risk for foodborne disease. For example, FDA/USDA developed a brochure specifically targeted at *E. coli* 0157:H7, "A Consumer's Guide to Safe Handling of Ground Meat and Ground Poultry."

We also directed information exchange efforts to health professional societies and medical journals so they can reinforce the public health advice to their members. We:

- alerted health professionals, using the June 1993 *FDA Medical Bulletin* which has a distribution of 1 million, to diagnose and report *E. coli* 0157:H7 diseases. Prevention advice was also included.
- provided, jointly, with the International Food Information Council Foundation, curriculum materials to high school teachers about foodborne disease.

Supplementing Industry Training Food Service Workers. Extensive training materials and programs have been developed by industry trade associations, private training companies, and state regulatory agencies for food service managers and workers. FDA supplements industry's efforts by focusing on those segments that serve people who are at higher risk of foodborne disease. Educational messages and up-to-date advice on food handling techniques are communicated to industry members through association newsletters, trade publications, conventions, and direct mailings. For example, during the last several years, FDA, CDC and the Health Care Financing Administration (HCFA) jointly developed a multi-faceted program for nursing homes. The program involved training the HCFA inspectors of nursing home food service facilities, a training video directed at the management and medical directors of nursing homes, and a training video directed at food service workers. In the past year FDA:

- updated the nursing home training materials to emphasize the risks caused by *E. coli* 0157:H7.
- developed with USDA "A Food Service Guide to Safe Handling of Ground Meat and Ground Poultry," and
- is currently developing a video teleconference training program on HACCP.

In summary, much FDA research and educational activities have been conducted during the year following the tragic *hemorrhagic colitis* outbreak that occurred in the Pacific Northwest. We will continue these activities, as well as our cooperation with CDC and USDA, to ensure that the American public has the safest food supply possible.

Thank you for allowing us to provide this statement. We will be pleased to respond to any questions the subcommittee might submit to us.

POLICY STATEMENT OF THE AMERICAN ASSOCIATION OF MEAT PROCESSORS ON HAZARDOUS ANALYSIS CRITICAL CONTROL POINT (HACCP)

(1) AAMP supports the HACCP concept, but believes that it should be thoroughly tested at various plant levels before any call for mandatory implementation is made.

(2) AAMP feels that the costs for implementing, operating, monitoring and auditing a HACCP program should be identified before any formal action is considered.

(3) AAMP believes that tolerance levels for various microorganisms should be established in advance of HACCP standards, making it possible to understand what is being controlled and creating criteria by which success or failure of a HACCP program can be measured. Implementation of any HACCP program without a standard of acceptable measurement for the organisms or pathogens that are to be controlled is ridiculous planning.

(4) AAMP supports a review of all options, including HACCP, discretionary inspection, or other methods to identify what level of microorganism and pathogen reduction is achievable and at what cost, both in set-up and in ongoing operation. The projected success of each option, and its cost should be identified, publicized and targeted for comment. For example, it may be that a consumer education program would be much more cost-effective than HACCP.

(5) Meat and poultry are not the only foods eaten on anyone's plate and to target these products for zero-risk while ignoring the dangers possible in other foods, or in food service or consumer handling of all items on the plate is irresponsible.

(6) AAMP supports all actions to assist in the development of a model small plant HACCP program, to help create a realistic, workable program to ensure the survival of smaller meat and poultry business and to assure the safety of their products.

(7) Implementation of any mandatory HACCP program should be phased in to allow adequate and reasonable time for affordable and effective programs to be implemented.

(8) Clarity on HACCP program ownership is needed, with public access to information and records or limits on their accessibility identified and standardized at the outset.

NATIONAL MILK PRODUCERS FEDERATION

The National Milk Producers Federation is a farm commodity organization representing nearly all the several hundred dairy marketing cooperatives serving the United States. Cooperatives market a substantial majority of the milk produced in the United States, making the National Milk Producers Federation—a most effective voice on national issues for dairy producers and the cooperatives they own and operate.

Mr. Chairman, and Subcommittee Members, the National Milk Producers Federation supports the new Clean Meat Program initiative of the U.S. Department of Agriculture. Likewise, we endorse other efforts by USDA to minimize the risk of pathogens entering the meat supply and reaching consumers. We applaud Secretary Epsy's efforts to reenergize enforcement efforts with 1,000 unannounced inspections of plants. Expanded enforcement coupled with expanded and coordinated training of in-plant personnel will reduce greatly the potential for contamination.

The Federation also endorses efforts of USDA to update slaughterhouse inspections with practical and reliable microbial detection assays. We support efforts underway to develop Hazard Analysis Critical Control Point quality assurance systems at both the preharvest and plant levels, provided such systems are grounded in science and are implemented without bringing unnecessary adversity to producers and processors.

We believe the emphasis on inspections and regulations need to shift from after-the-fact to a preventive mode. We believe USDA should be encouraged to develop and implement a HACCP based system of quality assurance with preventive microbiological quality control centered around appropriate critical control points in the production and processing system. If HACCP is properly employed, USDA's role as a pure after-the-fact regulator would shift to monitoring industries efforts.

The Federation supports and will participate in the NACCP development process. Animal identification and trace-back have proven to be essential elements in any successful control program. We, therefore, look forward to reviewing USDA's forthcoming legislative proposal which will provide the Department expanded authority to require animal identification and trace-back.

If USDA is to succeed in greatly reducing the risk of pathogens entering and reaching the consuming public through the meat supply, the Federation believes very strongly that two major areas of focus will be absolutely essential.

First, great emphasis must continue to be placed on educating food restaurant employees, and the consuming public, on proper meat handling, preparation and cooking, including mandatory labeling on how to avoid contamination, when purchasing raw beef or poultry. We believe the point(s) of meat preparation and cooking are the most critical of all control points in preventing outbreaks of public illness from pathogens such as *E. coli* 0157:H7. In spite of the success of efforts to minimize the presence of pathogens at the processing and preharvest levels, the virulence exhibited by many pathogens necessitates adequate cooking temperatures at all times and under all circumstances, coupled with proper procedures to avoid post cooking contamination.

Second, the ability to minimize or reduce the risk of pathogen entry into the meat supply at both the processing and preharvest levels requires a strong and continued commitment to funding research by the Congress. It will not be enough to emphasize just the development of new diagnostics capable of meeting expanded microbiological detection hopes at the processing level. Once developed, such diagnostics must be properly validated with protocols that are tested in the real world and under real conditions experienced at the farm and in processing plants.

While great emphasis can be given to expand genetic engineering and research into the genomes of cattle to produce bioengineered animals absent of unwanted pathogens, *serious efforts must be focused first on determining the molecular and ecological factors which foster initial colonization of cattle with particular strains of*

undesirable pathogens. Until more reliable answers are forthcoming on the existence of various pathogens in the environment and how such a presence can be practically controlled from the animal, we will be limited in the development of an effective HACCP system at the preharvest level.

Since the early 1900's, the United States has made tremendous progress in eradicating *brucellosis* and bovine tuberculosis from the Nation's cattle industry. Congress has been supportive of the eradication programs and needs to continue such support at this time when we finally have eradication in our eye-sight. The same level of persistence and Federal funding will be needed to achieve the eradication of pathogens such as *listeria* and *E. coli* 0157:H7, particularly at the farm level.

The dairy farmer members of National Milk Producers Federation recognize that the protection of public health is paramount to maintaining a viable and expanding market for milk and dairy beef. The Federation, therefore, will continue to take proactive positions to protect the Nation's milk and dairy beef supply. The Federation supports efforts of FDA and USDA to prevent microbial and residue contamination of dairy products and meat, and to reduce environmental contamination within processing plants.

If we are to succeed in greatly reducing the potential risks associated with uncooked meat products, a cooperative effort between industry, government and consumers is needed. While a total systems approach from the farm to the consumer is desirable, it is unlikely to happen unless a "spirit" of cooperation emerges. Government alone cannot resolve the problem, but if government can bring industry and consumers together to enjoin a cooperative effort, then there will be hope of making continued progress in preventing future illness and death from pathogens such as *E. coli* 0157:H7.

THE GOVERNMENT ACCOUNTABILITY PROJECT

Thank you for inviting the testimony of the Government Accountability Project. GAP is a non-profit, non-partisan organization whose purpose is to provide legal and other support for bona fide "whistleblowers", those individuals who make disclosures challenging alleged organizational misconduct where they work. Since 1981, GAP has represented over 150 whistleblowers from the Food Safety and Inspection Service ("FSIS"), more from that one agency than from any full cabinet department in the Federal Government. Further, GAP has represented over 75 corporate whistleblowers from the food industry. In some cases the representation has been to defend clients against alleged retaliation. In others, the goal has been to pursue their dissent more effectively.

Through advocacy for individual clients and membership in the Safe Food Coalition, GAP has played a leading role in public policy debates involving the safety of USDA-approved food. Examples involve Discretionary Inspection, Streamlined Border Inspection, Streamlined Inspection System for cattle, pork and poultry; the early HACCP proposals; occupational safety reforms, particularly after the Hamlet fire; and testing of beef for tuberculosis.

Last year the Department of Agriculture halted a pattern over the last decade of relentlessly weakening the food safety standards standing behind USDA's seal of approval. That is the good news.

Unfortunately, the bad news is more significant. USDA has not yet made serious progress in cleaning up the food supply. The steps taken last year are too late to help the victims of at least 17 food poisoning outbreaks nationally, and too little so far to prevent Jack-In-The-Box tragedies from happening over and over. This is unacceptable, because the public health threat is increasing geometrically. Estimates of food poisoning deaths have more than doubled in the last decade. Before last year's 17 outbreaks, there only had been 25 reported in the preceding 11 years.

In short, 1993 was a long-overdue beginning for USDA. Now the health of America's food inspection system is at a crossroads. Incremental change must be replaced by structural reform. Otherwise, food poisoning will be a way of life, or death, for consumers who rely on USDA's seal of approval.

GOOD NEWS

The bottom line is that consumers can realistically expect that USDA-approved food will not be filthier in 1994 than it was in 1993. This reverses a 12-year annual trend in which USDA-approved meat and poultry has been less wholesome than the year before. Food safety has bottomed out in dangerous depths, both for the health of consumers and meat industry markets. Between 6.5 and 80 million Americans suffer foodborne illnesses each year and 9,000 die, according to the Centers for Disease Control (CDC). Little more than a year ago, on the West Coast, over 500 people

became ill and four children died from *E. coli* 0157:H7 bacteria that was traced to insufficiently cooked, contaminated ground beef. Since then, there have been at least 16 clusters of *E. coli* poisoning cases from meat and other sources in more than a dozen states. The Department must begin the long, painful process of restoring wholesomeness to USDA approved food.

Second, Secretary Espy's new policy of zero tolerance for fecal contamination of meat in slaughter plants is an important initiative. Fecal matter is the carrier of *E. coli* and other dangerous bacteria. For the first time, consumers will not be purchasing Government-approved feces in any food except poultry. Up until now, small amounts of bovine feces were not only legal but were not even be counted as contamination. If zero tolerance directives are in fact applied in slaughtering plants, a major source of disease from meat will be substantially limited.

Third, Secretary Espy has taken a positive step in temporarily halting the USDA and meat industry's relentless ten year campaign for *de facto* deregulation by scrapping a planned HACCP (Hazard Analysis Critical Control Points) plan that would have institutionalized an honor system of industry self-inspection to vouch for USDA's seal of approval. The basic dynamic of the scrapped HACCP plan was that company personnel would actually be responsible for inspecting the food at critical points (CCP) where food poisoning germs accumulate. The companies also would pick those CCP's and set the pass-fail standards. USDA inspectors would check lower priority points on the line, and company records. That is a hopelessly inferior substitute for consumer protection. Often food is already out of the plant and on its way to the consumer when an inspector gets to the paperwork.

The meat industry has been trying since 1981, under different acronyms, to obtain USDA approval of a Streamlined Inspection System (515) for cattle similar to the 515 for poultry that was instituted in 1984 and caused the *Salmonella* rate to more than double for chicken. Consumer and public interest groups stopped USDA from allowing such a system—called *Discretionary Inspection*—for processed foods, and Congress killed 515 for cattle and pork.

Secretary Espy is to be applauded for listening to consumer groups, backing off from implementing HACCP by this past Labor Day, and deciding to start from scratch by holding a roundtable in mid-March with representatives from industry, consumer and public interest groups, scientists, and academics to work out a plan that has a consensus. Hopefully whatever new plan the USDA adopts will address public health and safety concerns as well as industry's interests. The roundtable offers an opportunity for creating a system that represents genuine modernization instead of phony modernization—a.k.a. deregulation.

Unfortunately, symptoms are appearing that the roundtable may be a public relations cover for the HACCP deregulation ghost that the industry and USDA's old guard bureaucracy refuse to give up. The warning signs are overwhelming.

- The membership is not balanced. The two token public health members, compared to nine representatives of industry and producers, confirm that the Agency's most publicized priority remains the black sheep in the bureaucratic closet.

- No follow-through process has been discussed.

- No new HACCP models have been floated as alternatives to the deregulation plan that supposedly had been scrapped.

- Secretary Espy publicly has analogized the New Turkey Inspection System, an 515 equivalent that is failing to produce wholesome products at 40 of plants in a recent USDA survey, as a model similar to what HACCP will be for the entire industry.

- No effort has been announced to prepare or consider public health standards to evaluate whether food passes or fails at the critical control points.

- There is *no* proof that current HACCP models have made the food supply safer. To the contrary, the studies to date consistently prove that wholesomeness decreases, or at best treads water under testing conditions far more sanitary than normal plant operations;

- The plan anticipates replacing Federal inspectors with corporate personnel without giving whistleblower protection to the latter, who can and are fired at will if they interfere with production by stopping the line or condemning products. In some giant plants, they even have been given production bonuses! Corporate inspectors cannot be expected to defend the public if they do not have the right to defend their jobs when they enforce the law.

- The models anticipate stripping public access to the new corporate rules of the game that will underlie USDA's seal, as well as the inspection results, by privatizing that information and denying it under the Freedom of Information Act.

Quite simply, unless the USDA restores its commitment to a genuine consensus starting from a clean slate, the public is not going to buy phony HACCP any more than it did the previous deregulation acronyms falsely advertised as scientific modernization. Former USDA Assistant Secretary Carol Foreman's testimony for the Safe Food Coalition lists the criteria for a public health HACCP program:

- state-of-the-art whistleblower protection for plant employees;
- additive to current inspection efforts, not substitutive;
- empirical proof that the combined HACCP and traditional inspection program produces safer, more wholesome food;
- compliance with professional quality control standards, such as approved training and certification of corporate personnel with key food safety responsibilities;
- scientifically-demonstrated basis that the critical control points are the most, dangerous and significant for public health;
- responsibility of USDA inspectors for the critical control points, with plant employees handling the remainder of food safety responsibilities under the supervision of Federal personnel;
- guidelines for acceptable levels of bacterial contamination;
- compliance with professional and National Academy of Sciences standards for the adequacy of testing and sampling programs.
- public access to all HACCP-generated information relevant to food safety, with no "privatization," compared to government data under the Freedom of Information Act;
- unannounced inspections of Federal personnel to check compliance the HACCP commitments;
- monthly publication of the names of plants that violate HACCP requirements; and
- civil fines for violators of HACCP or direct FSIS rules.

Fourth, Secretary Espy is to be commended for beginning the process of resolving the long-standing warfare between agency management and the union representing the inspectors. For the first time, management has begun to reach out to inspectors and work in partnership with them.

• Fifth, restoring the depleted inspection force has been an important step. To hire back 200 of 550 inspectors that the USDA is short in a period of budget cuts is indeed an accomplishment.

• Sixth, Secretary Espy has done much to end the USDA's "*fait accompli* syndrome." In the past, all plans and deliberations of the Department were secret until a proposal was formulated for consumer groups to react to, but Secretary Espy has begun a fairly regular practice of consultation with safe food advocates, consumer groups, and public interest groups.

Seventh, Secretary Espy has changed the Department's attitude toward whistleblowers by beginning to listen to them, rather than ignore or harass them. We appreciate that Secretary Espy came to GAP to meet with a group of whistleblowers and has invited individual inspectors to the Department for followup meetings with him. In addition, the Assistant Secretary of Agriculture for inspection has made it a point to read the disclosures of many inspectors regarding agency management. It is literally unprecedented that there is a line of communication between inspectors and agency's top leadership.

BAD NEWS

Unfortunately, despite these seven positive steps taken by USDA, seven fundamentally negative and dangerous trends continue. First, USDA hasn't yet begun the hard work of cleaning up the food supply, even to the point of restoring sanitation levels of 20 years ago. While the Department has halted the deterioration of the past 12 years, it has not begun to get meat and poultry back to the safety level where they should be and where American consumers can have confidence in the wholesomeness of the food they buy.

Second, poultry is just as contaminated as ever. In failing to extend the zero tolerance policy for fecal contamination to poultry, the USDA guarantees that the American consumer will continue to be provided with chicken that the Agencies own unpublished studies have confirmed have a 60-90° chance of being contaminated with bacteria such as *Salmonella*, *Campylobacter* and *Listeria*.

Third, USDA continues to engage in political science instead of the scientific method. Recent studies claiming improvements in poultry sanitation are unabashedly false advertising. The methodologies are so rigged that they have as much credibility as tobacco company ads saying that cigarettes do not cause any disease. To illustrate, a new "study" that USDA has been citing to the media for allegedly "proving" a drop in *Salmonella* to 28° in poultry, has the following flaws compared to a 1979-82 study that reported 37° levels. The methodology was deficient, because—

- it was not the same as in 1979, so the results do not reflect a consistent approach for a valid comparison;
- the sample size was too small;
- the testing methods were not sufficiently sensitive to catch the germs detected in 1982;
- the non-response rate of 30 percent from plants supposed to be covered was extremely high, suggesting that the dirtiest birds may have been withheld;
- the industry had advance notice of when samples would be collected, so the carcasses were not necessarily representative of dirtier products during routine operations;
- the measurements were taken before final packaging when there is opportunity for systematic cross-contamination, which left the results largely academic compared to what consumers actually get at the store.

It is interesting that USDA's public relations summary of this study omitted that the carcasses were almost uniformly contaminated with *campylobacter*, which is a cause of bloody diarrhea and other serious illness in its own right. It also is revealing that while USDA is touting this study, it failed to publish more honestly controlled studies finding 60-80° *salmonella* levels, including 100° after soaking in the common baths of fecal soup.

Fourth, USDA has been engaged in serious foot-dragging on setting up a system of rapid on-line laboratory tests for meat inspection. Meat and poultry inspection regulations have for decades been based on sight and smell techniques, which cannot ensure detection of invisible pathogens such as *E. coli* and *Salmonella*. To find bacterial contamination that isn't visible to naked eye, scientific testing is needed, and for the last 3 years, the National Academy of Sciences has called for such tests. When Secretary Espy took over the Department last year, he decided that the implementation of rapid on-line laboratory tests was going to be the cornerstone of his reform program, but so far nothing has happened. FSIS, the Agency responsible for inspection, has given one unsubstantiated excuse after the other for its failure to move on the implementation of these tests. Ten months after the Secretary's announcement that microbial inspection was of the highest priority for USDA, FSIS finally printed a notice in the FEDERAL REGISTER in mid-October for researchers to submit ideas for developing the technology for these tests. This prolonged procrastination on the so-called cornerstone of USDA's reform agenda and the key to modernizing inspection has been very discouraging. Recently touted tests suffer from such basic flaws as being too insensitive to catch lethal doses of food poisoning germs, and unable to distinguish between the various types of dangerous microbial contamination.

Fifth, the Department has still shown no willingness to establish standards for how much bacteria a carcass can contain before it's flunked. Developing rapid on-line tests for microbial contamination will not solve the problem of reducing the amount of *E. coli*, *Salmonella*, and other pathogens in meat when there is no standard beyond which contamination is illegal. USDA remains willing to even begin the process of determining safe levels so that some kind of public health standard can be established that flunks food that exceeds those levels and takes it out of the food supply.

Sixth, little or no progress has been made on cleaning up the border inspection program. This is an increasingly significant concern now because of open border trade agreements like NAFTA. For example, Mexico is notorious for having TB infected beef, which it can now more easily export to the United States. In addition, foreign nations have been dumping and are continuing to dump meat on American consumers that is unfit for their own citizens and that can't get past their own inspection system.

To add insult to injury, the USDA legalized imports of ground beef. This was an extremely dangerous step, because ground beef carries the highest risk for *E. coli*: bacteria is mixed throughout the beef as it is ground, and the germs can't be detected visually. *E. coli* and other pathogens can only be detected through scientific

tests, which the USDA does not do. Legalizing imports of ground beef is particularly unconscionable in light of the fact that imported beef was one of the prime suspects in the West Coast Jack-in-the Box tragedy.

Seventh, USDA last year approved the use of high pressure carcass sprays as a public health reform right after the Jack-In-The-Box tragedy. This was shamelessly cynical. The institution in 1978 of high pressure washing and to decontaminate chicken was public health travesty. Instead of requiring that fecal matter be cut off, as used to be done, USDA was convinced by the poultry industry to allow processors to avoid trimming off fecal-contaminated parts of carcasses or condemning them as contaminated and instead to put the carcasses through high pressure sprays that wash off the fecal stains. Although the washing makes the chickens look clean, it does not kill bacteria. In fact, the spray jets imbed the fecal matter in the skin and meat of the carcass. Moreover, this system spreads the contamination, particularly after all chickens soak in a common bath, known as fecal soup. As a result, the rate of *Salmonella* contamination of poultry has risen from 37 to 80 percent. Some unpublished studies even put the *Salmonella* infection rate after the chill tank at 100%. The washing also increases the weight of poultry because the carcasses absorb water.

The meat industry has been campaigning for years for carcass sprays so that it can better compete with the poultry industry, which is selling water for the price of chicken. Despite the meat industry's claims that carcass sprays will limit microbial contamination, no objective scientific study has proved this assertion. To the contrary, as the poultry industry has demonstrated, sprays cannot wash away contamination; rather they further imbed feces, milk or ingesta into meat surfaces that were previously clean. Data from the European Community, which bans carcass sprays, discredits the efficacy of such sprays in reducing contamination. Replacing the trimming of fecal material with carcass sprays represents a disastrous step backwards for beef safety, as it was for poultry safety. In addition, consumers will end up paying meat prices, as they now pay chicken prices, not just for water but for contaminated water.

In short, the Secretary's well-intentioned reform agenda has been effectively undercut by the same entrenched, arrogant bureaucracy that is responsible for the climate which produced Jack-In-The-Box and the other 16 outbreaks. It will take continued, determined leadership and stamina, by presidential appointees and Congress, to finish the job that Secretary Espy began. The stakes could not be higher. It is a matter of life and death for American consumers, and critical for the health of the meat industry.

LETTERS

NATIONAL GRANGE, OF THE ORDER OF PATRONS OF HUSBANDRY,
WASHINGTON, DC.

THE HONORABLE THOMAS DASCHLE,
Chairman, Senate Agriculture Subcommittee on Agricultural Research, Conservation, Forestry and General Legislation, Washington, DC. 20510-6000.

Dear MR. CHAIRMAN: The National Grange continues to be concerned about food safety and its influence on food policy. Of all the issues that impact public policy (food policy), food safety is the least understood.

Even though we have the most regulated, most inspected, and safest food supply in the world, the polls still show that Americans are still concerned about food safety. Why?

We believe there are several basic reasons. First, as people become more removed from the farm and depend more and more on others to grow and prepare our food, our understanding of how it is done decreases, and with it, our confidence in its safety. This might be called "the distance and dependence syndrome". Second, there is an underlying distrust in the Government's reports, news articles, and statistics that have conflicting conclusions about food safety. Third, this spark of distrust is fanned into an open flame by the periodic reports from special interest groups about the unhealthy characteristics of certain foods, chemicals, or food additives. These groups depend on sensationalism and emotionalism to instill fear in the general public in their effort to gain increased financial support.

Consumers are naturally confused. If they are going to err, they are inclined to err on the safe side. This confusion has challenged governments, scientists, and the

food industry to expedite their efforts to reform the food safety laws, particularly meat and poultry inspection in an effort to remove the perception in the consumers' minds that the food they eat is unsafe.

Consumers need better information on what makes food unsafe. How does it become unsafe? What is their responsibility in keeping food safe for their families?

Dr. David Kessler, Commissioner of the U.S. Food and Drug Administration, believes that we are paying too much attention to the role of pesticides at the expense of more pressing food safety concerns. Dr. Kessler says that bacterial contamination in food is the greatest threat to the public's health.

The *E. coli* outbreak in the Pacific Northwest that caused the death of several children drew attention to the Food Safety and Inspection Service, and led consumers to question the quality of our food safety inspection system. Increased and tighter inspections by more well trained inspectors will help, but that, in itself, will not assure a safer supply of meat and poultry products. The Secretary of Agriculture is to be commended for taking fast action on the *E. coli* outbreak in early 1993. The additional 400 inspectors will help, but we must do more to assure the consumer that the meat and poultry they buy will not harm their families.

As we now know, the outbreak was linked to undercooked ground beef that contained *E. coli*, a naturally occurring bacteria that can be found in or on raw meat. Although its presence can be reduced by the manner in which meat is processed and handled, proper cooking is the only sure way to destroy the bacteria. The system can and must be improved. Visual inspection must be supplemented by methods to inspect for harmful pathogens, such as *E. coli*. It will mean lowering the labor-intensive present visual inspection of every carcass and its internal organs and adding a Pathogen Reduction Program. Steps are underway within the U.S. Department of Agriculture to bring our inspection system into the 21st Century. The Grange will support this type of program.

The voting delegates to the National Grange's 127th Annual Convention, which was held in Cleveland, Ohio, in November of 1993, adopted the following resolution regarding meat inspection.

MEAT INSPECTION

WHEREAS, it is the Federal and/or state governments' responsibility to inspect meat and poultry intended for human consumption; and

WHEREAS, at the present time, there are not enough meat and poultry inspectors to enforce, or severe enough penalties imposed for violation of, the meat inspection laws; and

WHEREAS, potentially dangerous bacteria, such as E. coli, that is found on or in raw meat, cannot be detected by sight, feel, or smell; therefore be it

RESOLVED, that the National Grange support increasing the number of meat and poultry inspectors to supply continuous inspection of packing lines and that the meat inspection laws be strictly enforced, with increased financial penalties for repeat offenders; and be it further

RESOLVED, that we will support efforts by the U. S. Department of Agriculture in the development of a system of meat and poultry inspection that will detect the presence of microbiological pathogens, such as bacteria, and urges the Food and Drug Administration to develop specifications to permit irradiation of meat and poultry products to eliminate illness-causing pathogens.

It may take some time, but if we are to gain the consumers' confidence, the Federal meat inspection service must change. This will mean not only eliminating all chances of contamination during the slaughter and packing process but also including quick, inexpensive tests for the presence of harmful microbiological pathogens and a process for the removal of such pathogens.

It is our understanding that processes are now under study to accomplish the removal of *E. coli* and other pathogens from the food chain. We support these efforts.

We strongly recommend that irradiation of red meat be a vital part of this process. It is safe. It does not have any ill effects on food products or on those who consume them. We may have to go through the same educational process for food irradiation that we went through when we first started to homogenize milk. It was worth it in dairy products, and it will be worth it in red meat products.

If the above steps are taken, it will go a long way not only in supplying the consumer with the safest food in the world, but, more importantly, it will also help to remove the perception in the consumers' minds that red meat products are un-

safe. It will also aid, and make more acceptable, future educational program for consumers on food safety in the homes.

Thank you for asking the Grange for our comments on the Federal meat inspection service. It's good, but it can and must get better. Please include this letter as part of the hearing record.

Thank you.

Sincerely,

(SIGNED) ROBERT E. BARROW,

Master, National Grange of the Order of Patrons of Husbandry.

AMERICAN MEAT INSTITUTE,
Washington, DC.

THE HONORABLE MIKE ESPY,
Secretary of Agriculture, Washington, DC. 20250.

Dear MR. ESPY: The American Meat Institute (AMI) urges the U.S. Department of Agriculture to initiate and expedite rulemaking to mandate Hazard Analysis and Critical Control Point (HACCP) in the Nation's meat and poultry plants.

This new regulation should be consistent with the HACCP principles outlined by the National Advisory Committee on Microbiological Criteria for Foods, and comparable to the January 28, 1994 proposal to establish procedures for the safe processing, and importing of fish products by the Food and Drug Administration (FDA).

In 1992, the National Advisory Committee on Microbiological Criteria for Foods issued a report endorsing HACCP as "an effective and rational means of assuring food safety from harvest to consumption." The National Academy of Sciences endorsed HACCP in two 1985 reports as the best way to produce safe food, and HACCP has also earned the support of the scientific community, the food industry and the FDA.

USDA should complete the evolution to HACCP-based food production by mandating HACCP in the meat and poultry industry and by revolutionizing meat and poultry inspection to reflect a risk-based, prevention-oriented HACCP approach.

While AMI is prepared to take the first step towards a safer food supply through mandatory HACCP, we are adamantly opposed to a meat and poultry inspection system that maintains the *status quo*, while industry moves aggressively towards Government-mandated HACCP operations.

USDA's HACCP rule should be based upon the seven HACCP principles defined by the National Advisory Committee on Microbiological Criteria for Foods:

(1) *Conduct a hazard analysis.* Prepare a list of steps in the process where significant hazards occur and describe the preventative measures.

(2) *Identify the Critical Control Points (CCPs) in the process.*

(3) *Establish critical limits for preventative measures associated with each identified CCP.*

(4) *Establish CCP monitoring requirements.* Establish procedures for using the results of monitoring to adjust the process and maintain control.

(5) *Establish corrective action to be taken when monitoring indicates that there is a deviation from an established critical limit.*

(6) *Establish effective recordkeeping procedures that document the HACCP system.*

(7) *Establish procedures to verify that the HACCP system is working correctly.*

AMI urges USDA to make public health protection its primary goal in the development of a new HACCP regulation. Both HAS and the National Advisory Committee have stated that meat and poultry inspection would protect public health better if it focused more on hazards and control points related to public health (*i.e.*, pathogens and chemical agents) and less on aesthetic or economic issues unrelated to public health.

Furthermore, AMI encourages USDA to exercise its existing authority to encourage the use of HACCP at all points of the meat and poultry production chain, from farm to table. As the HAS stated in its 1985 report on meat and poultry inspection, "the most effective way to prevent or minimize hazards. in meat and poultry . . . is to control these agents at their point of entry into the food chain." We would remind USDA that meat and poultry packing and processing plants are not the only point where pathogens can be controlled.

The meat industry has long supported the HACCP approach and have been' active in implementing HACCP plans in plants throughout the U.S. AMI has actively participated in USDA's HACCP pilot study and we have developed and conducted a

number of industry HACCP training courses over the past 3 years, in cooperation with the Food Processors' Institute.

Working with USDA, we have already developed many critical control points for pathogens and are conducting research to identify more.

Mr. Secretary, in order for these new processes to work, we need a fundamental shift in approach to both food production and government oversight. Prevention must replace after-the-fact detection. Industry and government must embrace what the National Academy of Sciences has recommended since 1985; a commitment to preventing human health hazards in the food supply from farm to table.

Sincerely,

(SIGNED) J. PATRICK BOYLE,
President.

cc: AMI Board of Directors

UNIVERSITY OF WISCONSIN-MADISON,
MADISON, WISCONSIN, January 28, 1994.

The Honorable Senator THOMAS A DASCHLE,
317 Hart Senate Office Building, Washington, DC. 20510.

Dear Senator Daschle: Thank you for your letter of January 19, 1994, in which you invited me to submit written testimony to you about changes in, and effectiveness of, the Federal meat inspection program. I understand that the Subcommittee on Agricultural Research, Conservation, Forestry, and General Legislation will conduct a hearing on Thursday, February 10, 1994 at 9:30 am., in SR-332, and that my statement will be placed into the hearing record. I am pleased to provide you with the following statement.

I am professor of Meat Science and Muscle Biology at the University of Wisconsin. I have been employed in that position for 30 years as a teacher and researcher, in the areas of procedures for controlling properties and quality of meat, application of preservation techniques to meat, and assessment of safety of cured meat. I serve as a Food Science Communicator for the Institute of Food Technologists (a scientific society with 27,000 members), and I am chairman of the Food Safety Response Team for the Federation of American Societies of Food Animal Sciences (FASFAS). FASFAS is a coalition of four societies whose members are scientists working with animal and poultry production and utilization. I also work with CAST (Council for Agricultural Science and Technology), a coalition of 30 scientific societies devoted to advancing the understanding and use of food and agricultural science and technology in the public interest.

BACKGROUND

The present meat and poultry inspection system was commenced more than 80 years ago to prevent entry of diseased and damaged meat into the human consumption chain and to ensure that the operations converting food animals to meat were conducted in a sanitary and appropriate manner. The system worked well and continues to work well, for these functions. It is quite clear, however, that the animal production industry, the animal slaughter and meat processing industry, the distribution and retail industry, the food service business and the consumer have all changed significantly since the inception of the meat and poultry inspection system.

CHANGES NEEDED

Thus, the present inspection system must be modernized and improved. A more modern approach would emphasize microbiological hazards associated with meat processing and handling along with vigilance in preventing the entry of diseased and damaged meat into the marketplace.

University of Wisconsin-Madison provides equal opportunities in admission and employment.

Two key components, science and education, must be emphasized in the changes made. To achieve a modernized inspection system which addresses food safety risks:

- Technologies such as food irradiation, organic acid carcass rinses, and Hazard Analysis Critical Control Points systems must be adopted. Training programs in food safety—to educate inspectors, food plant personnel, and food service personnel—must be put in place. Likewise, unless educational programs for consumers are undertaken, the best scientifically based inspection program will not be successful. Consumers must understand food safety risks and proper food handling and preparation practices.

• We must be committed to the development and application of scientific advances. Among the shortcomings of the current science base are: 1) lack of sufficiently rapid microbiological detection and identification methods which are adaptable to routine use in, for example, HACCP systems, 2) insufficient knowledge of pathogen virulence and infectivity factors and of the prevalence and habitat of certain pathogens such as *Escherichia coli*. Thus, we must not overlook the critical need for research to provide the knowledge, currently lacking, upon which improved food safety systems depend.

CHANGES MADE AND UNDERWAY

You asked specifically about changes that are being implemented presently in the meat and poultry inspection system. Progress is indeed being made. As scientists struggle to find the optimum path to the safest food, they cannot be totally immune from political agendas and media activity; but such must not influence the basic scientific findings. Even though it may appear that progress is being made slowly, care must be taken when implementing changes of importance. It is quite necessary for all viewpoints to be heard and considered, after the scientific facts are in and before changes are made.

I believe the leadership of FSIS has done an outstanding job in attempting to modernize the meat and poultry inspection system. I must point out that changes were underway prior to the *E. coli* outbreak in ground beef just a year ago. Dr. Russell Cross was making real progress under most difficult circumstances. I consider it critical that a person of equal scientific qualifications be appointed to this position to ensure the program continues in an informed and objective manner.

In terms of real progress that has been made, I can enumerate the following. FSIS initiated a strategic plan termed the Two Track approach in 1992. Track I addressed short term issues and focused on improvement of the existing meat and poultry inspection system. Examples of accomplishments in Track I are: addition of a number of new inspectors, studies to establish baseline levels of various microorganisms in various meats, and the use of safe handling labels. While the implementation of safe handling labels experienced difficulty because of the rush to obtain approval, it is significant that many businesses are voluntarily using them. Encouragement has also been given to the industry to initiate HACCP programs which encompass the entire system from the farm to consumer. Track II is a revolutionary approach to rethink and rebuild the entire inspection system. FSIS has made a genuine effort to involve all parties and interest groups in the planning process. During early 1993 they conducted six public hearings around the country. During November 1993 FSIS organized a 2-day conference on the Regulatory Program of the Future. I participated in that conference and came away with a very positive feeling. The conference succeeded in opening dialogue amongst representatives of consumer, industry, professional, public health, FSIS employee and other groups interested in food safety. FSIS has worked hard to summarize comments from the above programs and make them publicly available in a timely manner. In summary, it is my opinion that the present meat and poultry inspection system accomplishes certain goals which must be maintained. On the other hand it fails in some respects and must be modernized to cope with modern production and processing operations and with the present-day consumer. FSIS is making real progress on both fronts and should be encouraged and provided resources to continue their plan. The program must be science based, and a consumer education component is equally necessary.

Sincerely,

(SIGNED) R. G. CASSENS,
Professor.

WILMER, CUTLER & PICKERING,
WASHINGTON, DC., February 4, 1993.

Ms. CAROL TUCKER FOREMAN,
*Safe Food Coalition, c/o Foreman & Heidepriem, Suite 750, 1112 Sixteenth Street,
NW., Washington, DC. 20036.*

Dear Carol: In the wake of the recent food poisoning tragedy involving USDA-inspected meat products in the state of Washington, questions have again arisen as to the authority of USDA to promulgate standards with respect to bacterial contamination of raw meat and poultry and to treat meat and poultry that fail to meet those standards as adulterated. Specifically, the argument continues to be made that a 1974 decision by the U.S. Court of Appeals for the D.C. Circuit in *American Public Health Association APHA v. Butz*, 511 F.2d 331, stands as a legal barrier to USDA

treating bacterially-contaminated meat and poultry as adulterated within the meaning of the Federal Meat Inspection Act (FMIA) and the Poultry Products Inspection Act (PPIA).

You have asked whether the APHA decision in fact precludes USDA from establishing standards for bacterial contamination and finding noncomplying meat and poultry to be adulterated within the meaning of the FMIA and PPIA. For the reasons discussed below, I conclude that it does not. USDA is free, on appropriate factual findings, to determine that meat or poultry that does not meet standards limiting the amount of harmful bacteria present in the meat or poultry is adulterated within the meaning of the statutes and therefore may not lawfully be sold.

Under section 1(m)(1) of the FMIA, 21 U.S.C. §601 (m)(1), meat is adulterated "if it bear or contains any poisonous or deleterious substance which may render it injurious to health; but in case the substance is not an added substance, such article shall not be considered adulterated under this clause if the quantity of such substance in or on such article does not ordinarily render it injurious to health." Section 4(g)(1) of the PPIA, 21 U.S.C. §453(g)(1), contains the same definition.

The APHA case did not involve the issue of adulteration as such, but rather the question whether, given the risk of bacterial contamination, meat and poultry should be deemed *misbranded* under the FMIA and the PPIA unless labeled with warnings to consumers about the possible presence of bacterial and directions for cooking and handling to assure safe use. A closely-divided court³⁵ held that regardless of whether bacterial contamination were viewed as rendering raw meat or poultry adulterated, USDA could reasonably conclude that the meat or poultry was not misbranded, even in the absence of any warning or directions for use. The court upheld USDA's exercise of discretion to determine that a general consumer education campaign was preferable to a labeling requirement.

To be sure, the court did state that "we think that the presence of *salmonellae* in meat does not constitute adulteration within this definition." 511 F.2d at 334. The court apparently accepted the Department's reasoning that because consumers are generally aware that proper handling and cooking of raw meat and poultry will eliminate the risk of illness from *salmonella*, the bacteria, as a naturally occurring contaminant, should not be regarded as "ordinarily" rendering the meat or poultry injurious to health. The court assumed that *salmonella* was an "inherent" contaminant subject to the more-difficult-to-show test of "ordinarily" rendering the product injurious to health rather than an "added substance" subject to the "may render" test.

A few years later, however, the same court of appeals characterized these statements about adulteration in APHA as dictum. *Continental Seafoods, Inc. v. Schweiker*, 674 F.2d 38, 41 (D.C. Cir. 1982). There the court, applying a similar definition of "adulteration" in the Food, Drug, and Cosmetic Act, found that APHA decision did not preclude FDA from treating *salmonella* as a substance that was "added" to shrimp and fining the *salmonella*-contaminated shrimp to be adulterated. See also *Seabrook National Foods, Inc. v. Harris*, 501 F Supp. 1086, 1092 (D.D.C. 1980).

In any event, the APHA court's statements with respect to adulteration were based on its acceptance of the factual premises of the Department at that time (more than 18 years ago)—factual premises relating to the state of knowledge of American consumers about proper methods of preparing and cooking food. The court may also have been influenced by the food. The court may also have been influenced by the unavailability of practical methods for detecting the presence of bacteria during the inspection process. Nothing in the APHA decision suggests that USDA is not free, upon appropriate findings, to conclude that the human health risk presented by the presence of bacteria in raw meat and poultry is sufficiently serious to render such products "ordinarily injurious to health."³⁶ USDA, as the expert agency charged with administration of the MIA and the PPIA, may take into account, for example, evidence that significant numbers of consumers are unaware of the cooking and handling precautions necessary to avoid the risk of illness; that such precautions are in any event often not followed (e.g., when the restaurant customer orders his hamburger "rare"); that the presence of bacteria is more common than previously thought; or that the ability to detect their presence has improved.

³⁵ The court was divided 2-1; Judge Robinson dissented, and was joined by two other judges (Bazelon and Wright) in voting for rehearing *en banc*. While rehearing was denied, Judge Leventhal, as discussed below, emphasized his view that USDA could take action if factual developments warranted.

³⁶ Nor does the decision preclude USDA from concluding, if there is a factual basis for such a finding, that there is sufficient human intervention in the process that leads to *E. coli* or other bacterial contamination to treat such bacteria as "added substances." If USDA so found, a conclusion of adulteration would readily follow. For there can be little doubt that significant amounts of *E. coli* "may render" the meat or poultry injurious to health."

Indeed, Judge Leventhal, in an opinion explaining his vote to deny rehearing *en banc* of the APHA decision, expressed his doubts about the Department's ability to educate consumers and cautioned that the court's decision did not "preclude a new challenge if it develops that consumer education programs prove inadequate to provide realistic protection." 511 F.2d at 338.

In short, the APHA decision stands at most for the proposition that USDA, on the factual record as it existed in 1974, was not required by the statute to treat *bacterially-contaminated meat and poultry* as adulterated. The decision in no way limits the Department's authority, upon appropriate findings, to establish standards for bacterial contamination and to treat products not meeting those standards as adulterated.

Please let me know if you have additional questions.

Sincerely,

(SIGNED) DANIEL MARCUS.

February 2, 1993

To: Pamela Gilbert, Director
Congress Watch

From: David C. Vladeck
Public Citizen Litigation Group

Re: Comments on January 22, 1993 Cross Memorandum *On the Outbreak of E. coli* 0157:H7 in Washington State

You requested that I review a January 22, 1993 memorandum from H. Russell Cross, Administrator, Food, Safety and Inspection Service, Department of Agriculture, which deals with the outbreak of *E. coli* contamination in Washington State. More specifically, you asked my opinion about Dr. Cross' discussion of the ramifications of *American Public Health Association v. Butz*, 511 F.2d 331 (D.C. Cir. 1974) (APHA). Dr. Cross' memorandum asserts that the APHA court held that "the presence of bacteria in raw meat and poultry does not constitute adulteration under the authorizing legislation," and that Congress did not intend the prescribed official inspection legends on meat and poultry products to import a finding that the products were free from *salmonellae* and other bacteria in that Congress did not intend that inspections include 'microscopic examinations'." Cross Memorandum, at 1.

Having carefully reviewed the Court's opinion in the case, and based on my knowledge and experience in this area, I am concerned that Dr. Cross' memorandum may be construed to suggest that the ruling (a) disables the USDA from using microscopic and other modes of analysis to determine the extent of *salmonellae* and bacterial contamination in meat and poultry and from setting microbial standards for raw meat and poultry, and (b) the presence of a rare bacterial strain in meat or poultry does not render the food product adulterated.

Neither of these conclusions is warranted. The case does not suggest that the USDA may not perform whatever technical analysis it believes is warranted to detect *salmonellae* and bacterial contamination. Nor does it forbid the USDA from concluding that meat or poultry contaminated with a rare or dangerous bacteria, or containing an infective dose level of bacteria, is adulterated. What is more, the opinion certainly leaves the USDA free to do what we have advocated for years: to set standards limiting the concentrations and strains of bacteria that may be present in meat and poultry products—standards, which, if exceeded, automatically render the food product adulterated.

In order to place the APHA ruling in its proper context, it is useful to focus on the underlying issues in that case. was a labelling case, not a challenge to USDA's inspection practices. The plaintiffs in the case alleged that—the official USDA labels that stated that the meat and poultry was "U.S. inspected" or "inspected. for wholesomeness" might constitute misbranding, because the labels failed to adequately explain to the consumer that the product may contain organisms capable of causing food poisoning or infection which would multiply unless the product is properly handled and cooked. The plaintiffs also argued that the labels should contain proper instructions on how to minimize such risks. Both the Meat and Poultry Acts prohibit misbranding.

In addressing the plaintiffs' claim that the absence of a warning about the danger of *salmonellae* rendered the product misbranded, the Court focused on whether the presence of *salmonellae* and other bacteria made the product "adulterated" under the Meat and Poultry Acts. To answer that question, the Court examined the

definition of adulteration, which is common to both Acts, and which defines the term as covering poisonous, deleterious or harmful additives and filthy or decomposed substances. A product is not considered "adulterated," however, if the deleterious substance does not "ordinarily, render the food product injurious to health.

The court found that the presence of *salmonellae* in meat or poultry does not necessarily make them adulterated *per se* for two reasons. First, the Court suggested, but did not hold, that the adulteration provision did not apply to substances such as *salmonella* which may be inherent in the meat or poultry. Second, the Court noted that, if proper food handling and preparation procedures are followed, *salmonellae* does not "ordinarily" render food injurious to health. In reaching this conclusion, the Court credited the Agriculture Department's claim that "the American consumer knows that raw meat and poultry are not sterile and, if handled improperly, perhaps could cause illness." APHA, 511 F.2d at 334. The court also pointed out that the presence of *salmonellae* or other bacteria can be detected only by microscopic examination. The Court noted, as the plaintiffs conceded, that it would be physically impossible for inspectors to perform microscopic examinations for each of the 10,000 birds poultry inspectors might examine each day.³⁷

Given the narrow focus on the decision, the implication in Dr. Cross' memorandum goes well beyond either the holding or dictum of the Court's ruling. To be sure, the Court recognized that the USDA could not be required to perform microscopic examinations on every single bird or every piece of beef inspected. However, nothing in the Court's opinion closes the door on substantial efforts by the Agency to use microscopic, and any other technical tools that might be available to it, to detect *salmonellae* or bacteria in food products. Indeed, consumer organizations have long advocated that USDA step up its monitoring activities.

Nor did the court hold that *salmonellae* or bacterial contamination could *never* make a food product adulterated. Surely, if USDA inspectors detected the presence of *salmonellae* or *E. coli* in concentrations or in strains that would ordinarily render the food product injurious to public health, then the product could be subject to the adulteration provisions of both the Meat and Poultry Acts. Equally important, the Court's opinion leaves USDA free to determine the amount of bacteria that would constitute an infective dose and would accordingly render it injurious to health—and thus subject to the Meat and Poultry Act's adulteration provisions. Finally, nothing in the opinion casts the slightest doubt on USDA authority to set standards restricting bacterial contamination, which, if exceeded, would automatically render & food product adulterated.

To place thin discussion in the context at the outbreak of foodborne contamination in Washington State, there are a few basic points. To begin with, there is simply no reason why the USDA inspectors at the Vons Meat Company plant that packed the Jack-In-The-Box hamburger could not have pulled out samples to analyze by microscopic and other technical means. Dr. Cross' memorandum appears to suggest that such testing is not ordinarily performed. Cross Memorandum, at 2.

If that is the case, the USDA's lack of vigilance is regrettable. Nonetheless, had such testing occurred, it is possible that this particularly dangerous strain of *E. coli* would have been identified. In that event, the USDA would have had the opportunity to consider whether meat containing this rare strain of *E. coli* is adulterated under the Meat Act, in that it presents an unreasonable risk to health, particularly since, insofar as am aware, meat must be cooked at a very high temperature for an unusually long period of time to destroy the bacteria. Had USDA proceeded in this manner, perhaps this public health crisis could have been averted.

If you have any further questions, please let me know.

³⁷ Judge Robinson found that the idea that most consumers are knowledgeable about the risks posed by *salmonellae* and other bacteria "is a debatable proposition," and noted that the record "contains fact supporting appellants' assertion that people are not generally aware of the danger of *salmonellae*, much less of the safeguards required to avoid *salmonellosis*." APHA 511 F.2d at 336 (Robinson, J., dissenting).

CRS Report for Congress

Foodborne Illness: Recent Outbreaks of *Escherichia Coli* 0157:H7

Donna U. Vogt
Analyst in Life Sciences
Science Policy Research Division

February 9, 1994



Congressional Research Service • The Library of Congress



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FOODBORNE ILLNESS: RECENT OUTBREAKS OF ESCHERICHIA COLI O157:H7

INTRODUCTION

Although the public has been concerned historically about pesticide residues in food, most public health officials and many scientists consider microbiological food contaminants--viruses, parasites, bacteria--to be a more serious problem. Foodborne illness from microbial contamination of food is estimated to cause from 6.5 to 33 million human illnesses and 6,000 deaths annually in the United States.¹ The bacterium *Escherichia coli* O157:H7 (commonly called *E. coli* O157:H7) has been found in raw and undercooked hamburger meat and caused more than 600 illnesses, 56 with serious complications and 4 deaths over the period January through March 1993. This development reawoke concerns about food safety in this country.

Federal, State, and local government agencies are charged with the responsibility of protecting the public against such outbreaks by enforcing regulations that are designed to ensure the food entering commerce is "safe." Agencies sharing regulatory responsibility interact to create a public health safety net to prevent foodborne illness. Such regulatory responsibilities cover surveillance, prevention and control, and consumer education. Surveillance involves identifying the causal bacteria, viruses, parasites, fungi, and/or protozoa causing foodborne illness and is chiefly the job of the Centers for Disease Control and Prevention (CDC), part of the Public Health Service (PHS). The U.S. Department of Agriculture's (USDA) Food Safety and Inspection Service (FSIS) and the Food and Drug Administration (FDA) strive to prevent contamination through targeted inspection, regulatory guidance, and education activities. FSIS is responsible for regulating and inspecting meat and poultry products. FDA is responsible for regulating the safety of all other foods. States and local health departments work closely with these Federal agencies. Each agency played a role in responding to recent outbreaks of illness from *E. coli* O157:H7.

Foodborne pathogens are difficult to investigate, control, and prevent. Laboratory testing may or may not detect which type of "bug" is causing the health problem. Foodborne pathogens constantly adapt and find new hosts; bacteria and viruses mutate over time. New scientific tests and epidemiological methods are now allowing CDC to determine that some illnesses of unknown

¹Weiss, Mike, Tanya Roberts, and Hal Linstrom. Food Safety Issues: Modernizing Meat Inspection. Agricultural Outlook. Economic Research Service. U.S. Dept. of Agriculture. June 1993. p. 33.

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cause are from foodborne pathogens. The Federal Government's response to these scientific changes tries to be flexible.

Consumers need to be educated as to proper food purchasing, handling, preparation, storage, and hygiene. Consumer education becomes important after food is sold at the retail level so that food remains "safe" along the food chain from the market to consumption. FDA estimates that 30 percent of foodborne illness involves unsafe food handling in the home.²

This paper reviews three outbreaks caused by *E. coli* O157:H7 in ground beef and apple cider. It describes the role Federal agencies played in these *E. coli* outbreaks, particularly an outbreak in 1993 in the West (hereafter known as the Western 1993 outbreak) and other food safety responsibilities. It then analyzes their experiences for lessons that can be derived.

What is *Escherichia coli* O157:H7?

E. coli O157:H7, a bacterium, produces a toxin which usually causes abdominal cramps and bloody diarrhea after three days, but may also cause a life-threatening complication known as Hemolytic Uremic Syndrome (HUS). HUS is a disease that affects the kidneys and the blood clotting system. In severe cases, kidney failure develops and dialysis is needed to take over the function of the kidneys, usually temporarily. The typical diarrheal *E. coli* illness consists of abdominal cramps and bloody diarrhea, with little or no fever. Some patients have non-bloody diarrhea; in others the bleeding is profuse. The illness can be easily misdiagnosed as inflammatory bowel disease. Other complications include dehydration, bleeding, seizures, intestinal perforation, and heart failure. Fortunately, the majority of people infected with *E. coli* O157:H7 do not develop HUS. However, from January to March 1993, of more than 600 people infected in four Western States, 4 died, and 56 developed HUS.

Most *E. coli* commonly present in foods are nonpathogenic. However, *E. coli* O157:H7 is a different strain or serotype. It has been found in a variety of food vehicles, including items of bovine origin such as ground beef, raw milk, yogurt, roast beef, as well as salad dressing, mayonnaise, and apple cider. It has also been found in unchlorinated municipal water and swimming water. The amount of bacteria required to cause the infection does not need to be large and the infection is easily transmitted person-to-person if careful hygiene practices are not followed. Heat used in cooking and pasteurization easily kills the bacteria.

***Escherichia coli* O157:H7 in Ground Beef and Apple Cider**

E. coli O157:H7 was first identified as a cause of illness in humans in 1982. Over the succeeding 11 years, 25 outbreaks were identified. For example, in October 1988, there was an outbreak of *E. coli* O157:H7 hemorrhagic colitis in

²Layden, William M. Food Safety: A Patchwork System. The GAO Journal. No. 15. Spring/Summer 1992. p. 56.

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a junior high school in Coon Rapids, Minnesota. The school had purchased pre-cooked beef patties from a large food processor. It was assumed that the patties were sufficiently cooked by the manufacturer to destroy enteric pathogens before they were frozen and distributed. The patties were then only warmed up in the school. Among 1,562 students, 32 became ill and four were hospitalized. No one developed HUS.

FSIS responded to this incident by publishing a two-part proposal first in December 1988 and again in June 1990 in the *Federal Register*, which gave cooking, handling, and labeling requirements for cooked (heat-processed, uncured) meat patties and partially-cooked or char-marked beef patties.³

Between October 24, 1991, and November 20, 1991, 23, people with *E. coli* O157:H7 were found to have consulted doctors in Massachusetts. CDC officials and the State of Massachusetts public health officials found that apple cider made at one mill was significantly associated with the illness. The mill pressed cider from unwashed and unbrushed "dropped" apples. The cider was not pasteurized, no preservatives were added, and the process was similar to that used by other small cider producers. No *E. coli* O157:H7 was isolated in the laboratory from the apple cider from the implicated mill. Later, in the laboratory, however, researchers found that *E. coli* O157:H7 could survive for 20 days in a sample of unpreserved refrigerated apple cider. In response to this finding, the FDA recommended that apple cider be pasteurized or a preservative such as sodium benzoate or citric acid be used. These additives reduce the *E. coli* O157:H7 survival to less than 7 days.⁴

From January to March of 1993, small children, the elderly who were already weakened by serious illness, and people with weakened immune systems (such as persons with AIDS) in four Western States (Washington, Idaho, California, and Nevada) were placed at risk of death by *E. coli* O157:H7 in one lot of ground beef. Before this outbreak was over, 600 people became ill and 4 died. This "Western 1993" incident resulted from eating undercooked hamburgers from a fast-food chain restaurant, Jack-in-the-Box. The hamburger used during that period came from Vons meat packing plant of El Monte, California, on November 19, 1992.⁵

³Regulations were first proposed in the *Federal Register* on December 27, 1988 (53 FR 52179) and again on June 5, 1990 (55 FR 23030).

⁴Besser, R. E., S. M. Lett, J. T. Weber, M. P. Doyle, T. J. Barrett, J. G. Wells, P. M. Griffin. An Outbreak of Diarrhea and Hemolytic Uremic Syndrome from *Escherichia coli* O157:H7 in Fresh-Pressed Apple Cider. *Journal of the American Medical Association (JAMA)*. Vol. 269, No. 17. May 5, 1993. p. 2217-2220.

⁵U.S. Dept. of Agriculture. Food Safety and Inspection System. Report on the *Escherichia coli* O157:H7 Outbreak in the Western States. May 21, 1993. p. 22.

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Federal Response to the Western 1993 *E. coli* O157:H7 Outbreak

On January 28, 1993, FDA published an advisory which recommended that all ground meat products be cooked in a manner to ensure that all parts of the food were uniformly heated to at least 68° C (155° F) for at least 8 seconds. It also recommended that the cooking process be systematically monitored to assure that the time/temperature parameters are met. FDA sent this advisory to all regional food program specialists, food service clients, and food handlers. It also prepared consumer brochures and a video for nursing homes personnel. In addition, Secretary of Agriculture, Mike Espy, appeared on several television talk shows in early February to reassure consumers that the *E. coli* pathogen are killed if hamburgers are cooked thoroughly.

In May 1993, FSIS published a final report on the *E. coli* incident.⁶ It drew several conclusions: 1) the strain of *E. coli* O157:H7 that caused the outbreak originated in a cow or cattle sent to slaughter; 2) procedures at the slaughtering, cutting, boning, and processing plants that provided the meat were in accordance with Federal standards; 3) slaughtering and dressing practices were the most likely means by which the meat became contaminated; 4) meat containing the pathogen *E. coli* O157:H7 was shipped to Vons and used to produce hamburger patties which were subsequently served at Jack-in-the-Box restaurants; 5) the hamburger patties were undercooked. (Prior to this outbreak, Washington State had required 155°F internal cooking temperature for all hamburgers; however, cooks in the Jack-in-the-Box chain said that they were unaware of this requirement.)

On August 2, 1993, FSIS published the final rule in the *Federal Register*, confirming its 1988 and 1990 proposed rule, which amended the Federal meat inspection regulations to specify:

heat-processing, cooling, handling, labeling, and storage requirements for certain uncured meat products, such as hamburgers, Salisbury steaks, breaded and battered chopped veal steaks, beef patties, and pork sausage patties. The amendment provides for the safe processing and handling and informative labeling of heat-processed (fully-cooked) uncured meat patties to assist in assuring that such products are wholesome and not adulterated or mislabeled when distributed to consumers.⁷

It increased the required internal temperature at the center of each patty to be at least 157°F for 10 seconds from 151°F for 41 seconds. Cooling instructions are also included. This rule had been drafted several years prior to the January 1993 *E. coli* O157:H7 outbreak.

⁶Tbid.

⁷U.S. Dept. of Agriculture. Food Safety and Inspection Service. 9 CFR Parts 318 and 320. Heat-Processing Procedures, Cooking Instructions, and Cooling, Handling, and Storage Requirements for Uncured Meat Patties. Final Rule. *Federal Register*. v. 58, no. 146. Aug. 2, 1993. p. 41138-41152.

Foodborne illness outbreaks are expensive. The costs to society of lost productivity and medical costs from the *E. coli* O157:H7 Western 1993 outbreak were estimated to be between \$229 and \$610 million.⁸ Federal officials estimated in 1988 that medical costs and productivity losses alone from all types of foodborne illnesses were in the range of \$4 to \$8 billion annually.⁹ This amount could be higher if other costs such as public health surveillance costs were included.

Documenting Outbreaks from *E. coli* O157:H7

When a series of cases (1 ill individual = 1 case) cannot be confirmed as being from the same source (e.g. the strain of *E. coli* O157:H7 has not been determined as being identical in all the cases) they are identified as clusters and not outbreaks.¹⁰ In 1993, over 16 clusters of sickness due to *E. coli* O157:H7 were identified in 12 States. Table 1 lists these clusters in States where they occurred, and the suspected food or vehicle that transmitted the *E. coli* O157:H7.

⁸Weiss, Mike, Tanya Roberts and Hal Linstron. Food Safety Issues: Modernizing Meat Inspection. Agricultural Outlook. Economic Research Service. U.S. Dept. of Agriculture. June 1993. p. 32.

⁹Roberts, Tanya and David Smallwood. Data Needs to Address Economic Issues in Food Safety. American Journal of Agricultural Economics. Aug. 1991. p. 933-942; Also see Garthright, W. E., D. L. Archer, and J. E. Kvenberg. Estimates of Incidence and Costs of Intestinal Infectious Diseases in the United States. Public Health Reports. No. 103 1988. pp. 107-116. Also see: Roberts, Tanya. Human Illness Costs of Foodborne Bacteria. American Journal of Agricultural Economics. Vol. 71, No. 2. May 1989. p. 473.

¹⁰Telephone conversation with Bob Irwin, District of Columbia Liaison Representative, Centers for Disease Control and Prevention (November 18, 1993), (202) 690-8598.

TABLE 1. Clusters of *E. coli* O157:H7 infections reported to CDC in 1993.

(preliminary data)

Outbreak No. for 1993	State	Suspect Food or Vehicle
93-1	Illinois	Unknown
93-2	North Carolina	Person-to Person
93-3	Pennsylvania	Ground beef
93-4	Oregon	Cantaloupe: possible cross-contamination with raw meat
93-5	Connecticut	Ground beef
93-6	Montana	Ground beef
93-7	New Mexico	Hot dogs
93-8	Massachusetts	Ground beef
93-9	Oregon	Mayonnaise
93-10	Oregon	Raw Milk
93-11	California	Ground beef
93-12	Maine	Unknown
93-13	Washington	Shredded cheese (non-dairy) from the salad bar
93-14	Washington	Pea salad; possible cross-contamination with raw beef
94-15	Texas	Unknown
93-16	Washington	Unknown

Source: Preliminary as of November 23, 1993. Dr. Patricia M. Griffin, Acting Chief, Foodborne Diseases Epidemiological Section, Division of Bacterial and Mycotic Diseases, National Center for Infectious Diseases, Centers for Disease Control and Prevention.

Documenting cases of *E. coli* O157:H7 has been particularly difficult since not all States report the disease to CDC in Atlanta, Georgia. Moreover, *E. coli* O157:H7 has been difficult to track because many States do not require that the disease be reported to the State's health department. However, it appears that most State public health departments are attempting to correct this shortcoming and are in the process of making *E. coli* O157:H7 a mandatory reportable disease.

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Complicating the reporting is that testing for *E. coli* is not easy for some laboratories; some do not know how to conduct the test and others simply are not testing. A special type of medium (Sorbitol-MacConkey medium and O157 antisera) is needed to detect the organism. Although readily available, few laboratories use it.¹¹

In the summer of 1993, Dr. Gus Birkhead, Director of the Bureau of Communicable Disease Control, New York State Department of Health, did a survey for the Council of State and Territorial Epidemiologists on reporting of *E. coli* O157:H7. He sent a survey to all 50 States and the District of Columbia asking if they had any requirements for reporting *E. coli* O157:H7. The responses are reported in Table 4.

Responses from the States are listed under four categories: "reports"; "in process"; "under serious consideration"; and "no plans." The category "reports" means that these States require that the physician and/or laboratory report any person known to contract an *E. coli* O157:H7 infection to the State Department of Health. Some States make the reporting of HUS a separate category; others combine it with *E. coli* O157:H7.

The category "in process" means that the State is currently in the process of changing its legal requirements on reporting *E. coli* O157:H7. Each State has a different process for making a disease "reportable." Some States must formally amend their sanitary code; others publish an intent to change the code, collect public comments, publish these comments, and publish a final ruling. In New York State, health officials must go before a State Board of Physicians who decide if the State Code should be amended.

The category "under serious consideration" means that State officials are considering whether to make *E. coli* O157:H7 a reportable disease. As of now, these States have not started the formal process of amending the State requirements.

The survey shows that 17 States have adopted a reporting requirement for *E. coli* O157:H7; 20 other States are in the process of amending their public health regulations or their statutes to require that the disease be reported. Eleven States (including the District of Columbia) are seriously considering making *E. coli* O157:H7 reportable, and three States have no plans so far.

¹¹Griffin, Patricia M. and Robert Tauxe. Epidemiologist at the Centers of Disease Control and Prevention. Unpublished Dear Colleague letter. Mar. 8, 1993.

TABLE 4. A Survey of the States on Reporting Cases of *E. coli* O157:H7

CATEGORY	STATES
reports	Connecticut, Idaho, Iowa, Michigan, Minnesota, Missouri, Nebraska, Nevada, New Jersey, New Mexico, New York, North Dakota, Oregon, Rhode Island, South Carolina, Vermont, Washington
in process	Arizona, Arkansas, California, Colorado, Hawaii, Illinois, Indiana, Kentucky, Maine, Massachusetts, Mississippi, Montana, New Hampshire, Ohio, Oklahoma, Pennsylvania, South Dakota, Texas, Utah, Wisconsin
under serious consideration	Alabama, Delaware, Florida, Kansas, Maryland, North Carolina, Tennessee, Virginia, West Virginia, Wyoming, District of Columbia
no plans	Alaska, Georgia, Louisiana

Source: Dr. Gus Birkhead, Council of State and Territorial Epidemiologist. New York, November 18, 1993. (518) 474-3187.

HOW THE REGULATORY SYSTEM WORKS AND ITS RESPONSE TO *E. COLI* O157:H7 OUTBREAKS

Each government agency plays a role in maintaining the safety net against foodborne illness outbreaks such as the *E. coli* O157:H7 outbreak. Each agency shares responsibility for surveillance, prevention, control and education. This report focuses on the Federal agencies role though, as it becomes clear below, the State and local authorities are the direct respondents and enforcing actors.

Surveillance

CDC coordinates surveillance activities throughout the country on all foodborne illness including *E. coli* O157:H7.

Centers for Disease Control and Prevention

When CDC officials learned of *E. coli* O157:H7 outbreaks in Minnesota, Massachusetts, and Washington, epidemiologists immediately flew out to these States to work with State officials investigating the causes and source of the illness. Such epidemiologic investigations helped to identify some people who had been misdiagnosed. The officials' identification of the *E. coli* O157:H7 pathogen likely saved many lives for it put doctors on alert across the States to be on the outlook for symptoms. Since then, CDC has continued to collect and analyze clusters of *E. coli* O157:H7 illnesses to determine if these should be investigated.

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Each year CDC publishes an updated list of infectious and communicable diseases that are transmitted through food handling. Enterohemorrhagic *Escherichia coli* (*E. coli* O157:H7) is a serotype of Enterohemorrhagic *Escherichia coli* is on this list as an actionable disease.¹² Such compiling and publishing of data on outbreaks is part of CDC's surveillance work and gives public health officials across the United States an awareness of foodborne illnesses to look for.

In its surveillance work, CDC assesses trends in data on the prevalence of etiologic agents, and in the vehicles (types of foods) of disease transmission. In fact, CDC surveillance efforts are often the first alert to a problem of concern to other Federal and State agencies with food safety responsibilities. CDC and State officials worked together taking case histories from the ill who appeared to have been infected with *E. coli* O157:H7.¹³ Washington State officials determined that faulty food-preparation practices in Jack-in-the-Box food-service establishments had to be corrected. CDC suggested to Washington State officials that they immediately notify day care centers of this outbreak.

The basis for most surveillance are reports to the CDC from States on occurrences of foodborne diseases. State health departments determine, in consultation with CDC, which diseases must be reported to them by physicians and diagnostic laboratories within their borders.¹⁴ These decisions are often made at meetings of the Conference of State and Territorial Epidemiologists. Then CDC tracks outbreaks in its Foodborne Disease Outbreak Surveillance System, and through other disease reporting systems such as the National *Salmonella* Surveillance System.¹⁵

Prevention and Control

Both FSIS and FDA play a major role in regulating and monitoring the food industry to prevent and control foodborne illness such as *E. coli* O157:H7.

¹²U.S. Dept. of Health and Human Services. Centers for Disease Control and Prevention. Diseases Transmitted through the Food Supply. *Federal Register*. v. 59, no. 9. January 13, 1994. p. 1949.

¹³CDC tries to determine the causation of the disease. However, in some cases, over half the pathogens responsible for foodborne illness go unidentified because 1) laboratory investigations are late or incomplete; 2) the pathogen may not be recognized as a cause of foodborne disease; or 3) because the pathogen can not be identified by available laboratory techniques.

¹⁴Tauxe, Robert V. The Role of Epidemiology in the Detection and Prevention of Foodborne Disease. Issues in Food Safety. Proceedings of a Joint Meeting of the Toxicology Forum and the Chinese Academy of Preventive Medicine, Beijing, October 16-20, 1988. Toxicology Forum, Washington, D.C. 1989. p. 40-46.

¹⁵This laboratory-based surveillance system depends on voluntary reporting by state health departments of *Salmonella* by laboratories. Most outbreaks reported through the Foodborne Disease Surveillance System were investigated without CDC's help.

Food Safety and Inspection Service

FSIS officials inspect at slaughter the meat and poultry entering U.S. commerce. Currently, through inspection and grading, FSIS enforces standards for wholesomeness and quality of meat and poultry. In principle, the meat industry must prove to FSIS that their product is wholesome before it can be marketed. In the slaughter operation, FSIS on-line inspectors, supervised by FSIS veterinarians, rely on sight, touch, and smell (organoleptic) inspection to detect disease or contamination of the meat. They can condemn carcasses which do not pass standards. FSIS also must approve in advance the premises, equipment, and operating procedures of a slaughter and/or meat and poultry processing establishment. After approval, the plant must continue to follow sanitary practices or the operation can be shut down by the FSIS veterinarian.¹⁶

FSIS officials hope to keep microbial contamination to a minimum by developing laboratory tests to quantify microbial and chemical risks associated with meat and poultry products, and by instituting a Hazard Analysis Critical Control Point (HACCP) system (see page 15). The HACCP system calls for a science-based analysis of potential hazards, decides where hazards can occur in processing, institutes measures to prevent problems, and decides which corrective measures are necessary if they do occur. Detailed HACCP record-keeping would allow FSIS regulators to monitor how well firms are performing.¹⁷

Food and Drug Administration

FDA responded within a few days to the January 1993 *E. coli* 0157:H7 outbreak with an advisory about internal temperatures and cooking times for ground beef. FDA is the agency primarily responsible in conjunction with the States, for ensuring the safety of the food supply at the retail level, including food service, vending machines, and food stores.¹⁸ However, it is not in the

¹⁶U.S. Library of Congress. Congressional Research Service. Meat and Poultry Inspection: Background and Current Issues. Report No. 93-574 ENR, by Geoffrey S. Becker. Washington, June 9, 1993.

¹⁷Routine activities of inspection and testing trigger a range of enforcement actions including product retention, product recall, and a temporary halt in production until problems are corrected. These activities attempt to protect the public by stimulating industry to correct unintentional violations, and to deter deliberate violations. FSIS can also pursue legal actions if these activities are not sufficient. U.S. Dept. of Agriculture. Food Safety and Inspection Service. Meat and Poultry Inspection. 1992 Report of the Secretary of Agriculture to the U.S. Congress. Sept. 1993. p. 23.

¹⁸Advisory guidance is given to the States and local governments upon request to meet specific needs. On the other hand, FDA regulations are more general and are the basic tool for achieving FDA's goal of consumer protection. FDA's regulations inform the affected industries and public of statutory requirements and FDA's procedures; they interpret the law and spell out the details needed to implement the general provisions of the statutes. Regulations also describe

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business of inspecting or pre-approving food products, except in rare instances.

FDA gives guidance to the food industry, and works with States and local governments to ensure that foods are nutritious, sanitary, and not adulterated or misbranded (misabeled). FDA carries out its objectives by: (1) encouraging self regulation by the food industry and promoting voluntary compliance; and (2) enforcing punitive provisions against those in the food industries who chose not to comply with FDA's regulations. The burden of proof is upon FDA to show that actual contamination has occurred or establish that conditions are unsanitary in the food processing plant. Working with the States and with the Department of Justice, FDA can prosecute violators.

FDA guides State and local governments in maintaining programs to prevent foodborne illness such as *E. coli* 0157:H7. In its 1993 Food Code, FDA outlines suggested regulations that it believes should be followed whenever State and local governments inspect food establishments.¹⁹ The Food Code is not preemptive of the States' right to establish their own regulations. The Code represents FDA's best advice for a uniform system of regulation to assure that food at the retail level is safe, and is properly protected and presented.

FDA regulations also provide consumer protection. Foods are monitored to identify processing conditions that may cause products to be unsafe or to identify products which may present health hazards. For example, FDA found that *E. coli* 0157:H7 could grow in unpasteurized cider for 20 days. FDA recommended that apple cider be pasteurized or a preservative added to reduce the *E. coli* 0157:H7 survival to less than 7 days.²⁰

the approval processes for many individual products or set forth required standards of product composition or performance. Most FDA regulations have the force and effect of law.

¹⁹ Authority for this activity comes from the Public Health Service Act (P.L. 78-410). Section 211 [42 U.S.C. 243] states that

The Secretary shall ... assist states and their political subdivisions in the prevention and suppression of communicable diseases, shall cooperate with and aid state and local authorities and in the enforcement of their ... health regulations and ... shall advise the several states on matters relating to the preservation and improvement of public health.

Responsibility for carrying out the provisions of the Act relative to food protection was transferred to the Commissioner of Food and Drugs in 1968 [21 CFR 5.1(a)(2) and (4)]. Thomas Schwarz, Science Policy Advisor, Center for Food Safety and Applied Nutrition. U.S. Food and Drug Admin. Dec. 13, 1993. (202) 205-5140.

²⁰ FDA requires that three categories of foods get pre-market approval before entering interstate commerce: food additives, low-acid canned foods, and foods carrying health claims on their labels. Otherwise, foods do not now need any further guidance prior to being sold in retail stores.

Consumer Education

For direct consumer education, FSIS, FDA, and CDC have telephone hotline systems to answer specific questions about problems, publish educational materials such as brochures for special populations, and, through specialists in the field, they make efforts to educate the public to avoid mishandling foods.

Consumers are told through various media how to handle food in a safe and sanitary manner. Most of the suggestions appear to be standard or basic care and involve the concepts of time, temperature, and cleanliness. For example, limit the time food is out of the refrigerator before eating; store leftovers promptly; cook thoroughly if required; keep hot foods hot and cold foods cold (keep foods out of the danger zone of 45° to 140° for extended periods of time); keep foods properly refrigerated if called for; wash your hands before preparing or eating food; check "sell by" or "use by" dates ("when in doubt, throw it out"); use proper sewage disposal; avoid unpasteurized milk and unchlorinated water; sanitize utensils and cutting boards before and after preparing raw foods and each food item; check foods for visible mold and discard those that are contaminated; avoid raw fruits and vegetables grown in areas where protozoa are rampant. A central fact is that it is impossible to ensure that all domestic and imported foods are free of pathogens. But if standard practices such as these are used, they mitigate much growth of pathogens in foods.²¹

OPTIONS

Some analysts contend that the current food safety system needs a number of improvements; some improvements are underway, while others are still being discussed. This section analyzes four actions that have been proposed. FSIS may be improving laboratory testing which can routinely detect *E. coli* O157:H7. Some officials see a need to increase epidemiological data bases where illnesses are recorded. Consumers need further education on reporting illness and on safe handling and cooking practices. Agencies are planning a few changes in their slaughter and inspection systems.

Improve Laboratory Testing Methodologies

On October 21, 1993, FSIS published in the *Federal Register* a notice to inform interested parties of the criteria FSIS wants to develop for new microbiological testing methods.²² Critics claim that FSIS should have already developed rapid on-site laboratory tests for *E. coli* O157:H7 as well as other pathogens long before the January 1993 outbreak occurred. Their reasoning is that regulators and policy makers should be monitoring carefully the levels of microbial or chemical hazards in meats and other foods. But even with better

²¹Conversation with Ms. Carole Schiffman, Office of Constituent Operations, Director of Consumer Education Staff. Food and Drug Administration. December 17, 1993.

²²U.S. Dept. of Agriculture. Food Safety and Inspection Service. Criteria for Evaluation of Rapid Microbiological Testing Methods. *Federal Register*. v. 58, no. 202. Oct. 21, 1993. p. 54325.

tests, it is still important to maintain control along the entire food chain, according to critics. Others question whether better testing methods and more data will improve the safety of meats.

Expand Epidemiologic Data Bases

CDC officials are encouraged by the response from the States to the *E. coli* outbreak in 1993. It appears that 37 States are well along in the process of making the reporting *E. coli* 0157:H7 cases mandatory. However, regulators could use an expanded tracking system for microbial risks and their links to food vehicles and other health survey data. Prompt and complete epidemiological data help in developing policies to guide effective regulatory control programs. Data on cases of foodborne illnesses also assist to prevent reoccurrences of illness, and to help prioritize and evaluate risk management efforts.²³ CDC is collecting epidemiological data and studies making causal or association links to *E. coli* 0175:H7; some critics are concerned that the resources being allocated to collect this data are too small and will not increase under current fiscal constraints.

Educate Consumers on Prevention

Consumers need instruction on how to cook and handle food. FDA worked closely with FSIS and CDC in sending out alerts to their field offices and the States about *E. coli* 0157:H7 and other etiologic agents with public health food advisories. Both agencies prepared videos and training materials regarding *E. coli*, and held workshops to teach about controlling risks at critical points in the handling of foods for a variety of pathogens. CDC is creating a video to help educate clinical microbiologists on the isolation and identification of *E. coli* 0157:H7. Consumer education becomes important after food is sold at the retail level so that food remains "safe" from the market to consumption.²⁴

Consumers will, by April 15, 1994, begin seeing safe-handling labels on all uncooked meat and poultry products. The new label, required by FSIS, does not warn of health hazards in the meat.²⁵ It does recommend thorough cooking.

²³Data on foodborne illnesses is underreported. People with diarrhea seldom report their condition if it lasts a short time, or if they feel better quickly. Most people do not seek medical attention. When diarrhea illness is associated with specific foods or meals, and the condition is reported to doctors, the remains of the meal may have been thrown out or it may be too late to take a stool sample to determine the cause. If the diarrhea is serious and ongoing, a doctor or laboratory may do a stool sample, and if a specific pathogen (bacteria or virus) or a chemical agent, which has been identified on the reporting list by the State public health officials, is found, the doctor or laboratory will report it on a specific form. Such an indirect tracking method has made CDC's job more difficult.

²⁴Layden, William M. Food Safety: A Patchwork System. The GAO Journal. no. 15. Spring/Summer 1992. p. 51.

²⁵Egan, Timothy. A Year Later, Raw Meat Still Lacks Labels. New York Times. Dec. 20, 1993. p. A1, D10.

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FDA has also advised the States to increase their minimum temperature requirements for cooking hamburger to 155°F.

Many of the people who became ill in the *E. coli* 0157:H7 outbreak had eaten in the Jack-in-the-Box fast food chain. Some argue and others dispute that the risks of foodborne illness affecting more consumers may increase as people rely on others to prepare their foods. The higher-risk population (children, the elderly) are having more meals prepared outside the home--in day-care centers, nursing homes, and home-delivered meals. The CDC has stated that, of the reported foodborne illness outbreaks caused by mishandling, most occurred in retail food establishments where the food was prepared for public or institutional consumption.²⁶

Improve Inspection System

According to many food safety experts, the biggest challenge to the industry may be to minimize or eliminate potential infectious enteric bacteria in slaughtered animals. FSIS rules have important impacts on quality, but sometimes have been ineffective in preventing contamination by disease-causing bacteria. In the 1985 report of the National Academy of Sciences, Committee on the Scientific Basis of the Nation's Meat and Poultry Inspection Program, the committee recommended that FSIS institute a system at the slaughter point to ensure that the removal of digestive tracts from animals be done in a manner that will prevent contamination of edible tissues.²⁷ The industry is supporting new systems and procedures to minimize just such contamination because it has been shown that *E. coli* 0157:H7 tend to live in cattle intestines.

The outbreak of illness due to *E. coli* 0157:H7 has led the FSIS to consider instituting a different strategy for its meat and poultry inspection. USDA will soon start conducting on-farm tests to identify pathogens under its Pathogen Reduction Program (PRP). FSIS will also increase its education of food service workers and is creating a new division to oversee public health activities within the agency such as investigations, epidemiological analyses, and product recalls. Critics are concerned with the inability of the current system to address microbial contamination such as *E. coli* 0157:H7 in the meat processing system.

A further attempt at reforming the current system is the HACCP system which FDA and USDA have both identified as the most effective strategy for controlling disease-causing pathogens in food products.²⁸ Officials from both

²⁶Source: Centers for Disease Control. Morbidity and Mortality Weekly Report (MMWR) CDC Surveillance Summaries. v. 39. no. SS-1. Mar. 1990; and 1988-91 numbers (draft) from CDC.

²⁷National Academy of Sciences. National Research Council. Meat and Poultry Inspection: The Scientific Basis of the Nation's Program, Washington, D.C. 1985.

²⁸U.S. Department of Agriculture. Food Safety and Inspection Service. FSIS Information Office. FSIS Backgrounder: Hazard Analysis and Critical Control Point (HACCP) Systems. July 1993.

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agencies are working with their regulated industries to design HACCP programs that will identify critical points of risk and reduce the potential for introducing *E. coli* 0157:H7 and other foodborne pathogens in the processing and preparing of foods. In fact, other groups are also supportive of reforming the inspection system using HACCP principles. The National Advisory Committee on Microbiological Criteria for Foods has adopted of a series of HACCP recommendations for raw meat.



REVIEW OF USDA'S "ZERO TOLERANCE" MEAT INSPECTION POLICY

TUESDAY, MAY 24, 1994

U.S. SENATE,
SUBCOMMITTEE ON AGRICULTURAL RESEARCH,
CONSERVATION, AND FORESTRY, COMMITTEE ON
AGRICULTURE, NUTRITION, AND FORESTRY,
Washington, DC.

The subcommittee met, pursuant to notice, at 9:37 a.m., in room SR-332, Russell Senate Office Building, Hon. J. Robert Kerrey presiding.

Present or submitting a statement: Senators Kerrey, Daschle and Craig.

STATEMENT OF J. ROBERT KERREY, A U.S. SENATOR FROM NEBRASKA

Senator KERREY. This hearing of the Subcommittee on Agricultural Research, Conservation and Forestry will now come to order. Today, the subcommittee will review the USDA's zero tolerance meat inspection policy. I need to first thank the Chairman of the full committee, Senator Leahy and the Chairman of the subcommittee, Senator Daschle, for their cooperation in scheduling the hearing this morning. I want to thank the witnesses, in particular, who have agreed to come here this morning on short notice, and I look forward not just to your testimony but to having a discussion of this issue.

This Zero Tolerance Policy, and the *E. coli* outbreak which led to it, resonates with a substantial immediacy in the State of Nebraska. We find ourselves on both sides of the concern.

First, over the past month at least 21 Nebraskans became ill following an *E. coli* outbreak that apparently has been traced to the hamburger they consumed. Fortunately, no one died from the incident, but some of these young people were taking seriously ill. We do not know yet if the product in this instance was simply mishandled, but we do know that for these victims, the existing Zero Tolerance Policy by itself failed to ensure the necessary margin of safety.

Second, the cattle feeders in our State bear the regulatory cost of zero tolerance perhaps more than producers in other States because finished cattle in Nebraska are sold predominantly on a carcass weight-and-grade basis, rather than live, on-the-hoof, as is the prevalent practice in most other States. Because cattle in Nebraska are sold on a carcass weight basis, any additional carcass

trim that is required by zero tolerance comes directly out of the pocket of Nebraska producers at an estimated cost of about \$10-a-head, or about \$60 million a year in a single State.

For similar reasons, meat processors are concerned about a policy that, by USDA's own admission, is unevenly enforced from plant to plant, and that results in reduced line speeds and occasional stoppages.

In other words, there is something for consumers, producers, and processors alike to find lacking with the current inspection system. That raises a basic question and that is the purpose of a this hearing. "That question is, 'Is there a better way? Is there a better procedure or procedures that will allow us to remove fecal material in a more effective and efficient manner and do a better job of reducing the bacterial count in meat? If so, what are those procedures and what are the prospects for having them in place in the foreseeable future?'"

I know that Secretary Espy is determined to move forward on this issue. He moved very decisively last year. I know his personal commitment to ensuring the safest possible supply of food to the consumer is unquestioned. However, I sense a growing undercurrent of frustration among all, who are following this issue, that we are not moving quickly enough, or with sufficient steadfastness to get this issue off dead center. I hope this morning we can learn more about the game plan and timetable that USDA has in mind to move us to the modern, risk-based inspection system that most everyone seems to advocate.

Senator Craig, do you have an opening statement?

STATEMENT OF LARRY E. CRAIG, A U.S. SENATOR FROM IDAHO

Senator CRAIG. Mr. Chairman, let me thank you for urging and ultimately getting this hearing into reality. I have been a part of looking into the *E. coli* outbreak issue for some time and you are absolutely right, it is a problem that we will deal with and we must deal with. We lost people in the Pacific Northwest, as a result of the consumption of some tainted meat product. We at that time had encouraged the Department to move rapidly, yet that has just not occurred in a way that we think it should.

We also in a hearing some months ago in discussing trim versus wash, began to recognize that new techniques are necessary; that just hiring more people to man an old process that is not working very well is not a way you solve this problem; that there are new techniques. One of them that had been discussed at that time that the industry has looked at was washing the carcass instead of trimming and putting at risk greater exposure. All of those things are out there and we ought to be resolving this a good deal more faster than we are.

I am not at all pleased that the Department has taken as long as it has. It is an issue where I think the facts can be looked at in reasonable fashion and that we can make some decisions that are good for the consumer, and at the same time, good for the producer. Your situation, as you explained it in Nebraska, is not totally unique. Producers in my State are at the same time very concerned that we have not moved in a responsible fashion; that just

to create higher rates of trim does not necessarily solve the problem; it costs money; when there are new techniques that are out there. We have talked, I have, at length with the industry about the development of a HACCP approach that resolves this issue in a more reasonable fashion.

Bottom line is, we need to get it done. Get it done quickly, responsibly, so that we can assure the consuming industry that the meat they buy on the market shelf is safe. While we can say that it is very much largely safe today, there are those problems that have to be dealt with. When statistics show that only 5 percent of the problem occurs outside the home, then we need to resolve that portion of it as best we can and get on with it.

I thank you for the timeliness of these hearings. I am anxious to hear the response of the panel members. It is very important for this administration and for USDA to understand that we are going to continue to push until there is resolution to this problem and it must be done in a timely fashion. It must be done in a responsible way to keep our producers alive and to convince or to cause the public, as consumers, to know that they are going to get a safe product on the shelf. Thank you.

Senator KERREY. Thank you very much, Senator Craig.

I will call the panel up now. Ms. Pat Jensen, the Assistant Secretary for Marketing and Inspection Services, U.S. Department of Agriculture; John Harman, Director, Food and Agriculture Issues, Resources, Community, and Economic Development Division of the U.S. General Accounting Office; Pat Boyle, President and CEO of American Meat Institute; Carol Tucker Foreman, Coordinator, Safe Food Coalition and President, Foreman and Heiderpriem, Inc.; and Gary Wilson, Director of Animal Health/Inspection and Research Committees of the National Cattlemen's Association.

Good morning. Secretary Jensen, we will begin with you.

STATEMENT OF PATRICIA JENSEN, ACTING ASSISTANT SECRETARY FOR MARKETING AND INSPECTION SERVICES, U.S. DEPARTMENT OF AGRICULTURE, WASHINGTON, DC.

Ms. JENSEN. Thank you, Mr. Chairman, and Members of the subcommittee. It is a pleasure to appear before you today to discuss the Department of Agriculture's activities to improve the meat and poultry inspection system.

Secretary Espy and I take our mission to protect the public health very seriously. Unfortunate as they are, the continuing sporadic outbreak of foodborne illness caused by pathogens are forceful reminders of the urgency of our assignment. I have a written statement that I would like to have put in the record, Mr. Chairman.

Senator KERREY. Without objection, it will be included.

Ms. JENSEN. Early last year, Secretary Espy laid out a strategic pathogen reduction plan that addressed steps of the farm to table continuum where the potential for food safety problems may be reduced. The Secretary's strategic plan is based on risk principles advocated by the National Academy of Sciences and the General Accounting Office in their recommendations for improving the safety of the Nation's food supply.

As I reported in February, we have over 70 initiatives underway in the agencies under Marketing and Inspection Services. I would like to discuss very briefly just a few of those at this time.

On the enforcement side to safeguard public health, Secretary Espy has directed FSIS to emphasis stricter enforcement of sanitation and other food safety requirements in meat and poultry plants. To control a potential source of pathogenic bacterial contamination, the meat and poultry industry must produce carcasses that are as free of fecal matter, ingesta and milk contamination as possible. At this time trimming is the only approved means for removing such contaminants from beef carcasses.

USDA through the Cooperative State Research Service awarded a cooperative agreement on the basis of competition for the conduct of a study to determine the relative efficacy of trimming versus washing of beef carcasses to remove pathogenic bacteria during beef slaughter operations. This study is now being conducted at Texas A&M University to evaluate trimming, water washing and organic acid washing treatments and results are due to us by December of 1994. These results and other scientific information will be used to update our policy at that time.

Secretary Espy has announced that USDA will further enhance and strengthen the poultry inspection system to include microbial improvements and the prohibition of all fecal matter on raw poultry product. This reinforces the Zero Tolerance Standard for Poultry. In 1993, scientists completed a study that reconfirmed previous studies establishing the efficacy of washing of poultry, and as a result, we will continue to permit washing as a means of reprocessing poultry that is accidentally contaminated by fecal material. New regulatory proposals under consideration would place additional requirements on the industry to control fecal contamination during the poultry slaughter process.

The Secretary has also directed FSIS to establish a new review and assessment division and last fall the review and assessment office began a series of 1,000 unannounced meat and poultry reviews throughout the United States. These reviews are targeting meat and poultry plants suspected of having compliance problems and also a significant number of other plants selected to provide a general profile of industry compliance.

Through Secretary Espy's efforts over the last year and as a part of the President's fiscal year 1994 food safety investment initiative, additional inspector positions have been filled at FSIS.

There is a new public health emphasis at USDA. To improve coordination with public health officials, Secretary Espy directed FSIS to create a new liaison position with CDC. In addition to the FSIS CDC position, the Animal and Plant Health Inspection Service, APHIS, also has a full time veterinary epidemiologist to facilitate communication and coordination between APHIS and CDC. Secretary Espy directed FSIS to officially establish a Public Health Division. This division has been established and will assume the responsibility of establishing public health programs and policies and maintaining liaison with Federal, State, and local government officials involved in the detection and control of foodborne disease.

In addition, the Public Health Division will coordinate FSIS' response to emergency situations affecting the acceptability of meal

and poultry products, coordinate voluntary recalls of contaminated product and operate a foodborne hazard control center.

A few words about HACCP. USDA is drafting a proposed rule that would require that the meat and poultry industry incorporate the HACCP approach in food production systems. The HACCP approach involves identifying critical control points and establishing critical limits for each critical control point. Each critical control point must have one or more measures that must be monitored to assure process control. Some of these measures or critical limits are established from chemical, microbial or physical guidelines.

As to risk assessment, Secretary Espy is committed to moving meat and poultry inspection from organoleptic examination to one that is more risk based and grounded in the latest science. A major objective of USDA's current research program is to determine the exact nature of risk associated with bacterial contamination of meat and poultry during slaughter and processing.

Our focus is not only on the slaughter and the processing plants, it also includes the entire food chain from the farm to the table, and for this reason, the pathogen reduction program includes a preharvest food safety focus also. This focus deals with the beginning of the food chain on the farm where the meat and poultry production begins and it continues through transportation to the slaughter house.

Pre-harvest food safety activities are primarily the responsibility of the Department's Animal and Plant Health Inspection Service, APHIS. We already have in each State an infrastructure ideally suited to conducting emergency trace-back investigations and we periodically conduct mock animal disease emergencies to keep our field work force and investigation techniques well honed in the event of a real emergency and we work this through APHIS.

On microbiological testing, an important component of Secretary Espy's strategic plan is nationwide microbial baseline studies to determine the presence and levels of pathogens on meat and poultry. These profiles will give USDA the critical yardsticks that we need against which to measure progress to reduce risks associated with microbial contaminants. Rapid detection of microbial contamination on meat and poultry products is a major goal at USDA.

Using bioluminescence technology is an example of USDA research in this area. USDA's Agricultural Research Service, ARS, is developing a rapid test at its Clay Center, Nebraska, and its Athens, Georgia, laboratories. It is hoped that the ATP bioluminescence test will be able to detect within 5 minutes relatively high levels of general bacteria on carcasses. It is thought to be as accurate and repeatable as the 48-hour plate culture test currently used in laboratories to determine bacterial levels. This test shows promise for supplementing FSIS visual detection of fecal contamination on carcasses.

FSIS is also embarking on a major initiative to integrate microbiological testing throughout the inspection system. This is being done in three phases. First is preoperational sanitation. FSIS will employ random micro-monitoring to supplement daily

visual inspection of plant sanitation programs. Second is during the slaughter process, when FSIS will begin microbiological monitoring of carcasses before they enter the cooler. These results can be used to trace the plants process control system to minimize bacterial contamination.

FSIS is also extending its current microbiological testing program for processed, ready-to-eat products to additional types of products not currently covered.

I would like to say just a few words about consumer education also, because another part of the pathogen reduction program is consumer education. As of May 27, all raw and partially cooked ground meat and poultry products, such as hamburger and sausage, must bear a safe handling and cooking label. All other not-ready-to-eat meat and poultry products must have the label by July 6 which coincides with the date that USDA will require nutrition labeling.

We would like to applaud at this time the many members of the food industry who are already labeling their products with safe cooking and handling instructions. Earlier this month I was in Atlanta to launch a food safety education campaign targeting children and parents coast-to-coast with the announcement of the distribution of more than two million post cards bearing an important message about only eating thoroughly cooked hamburgers that are brown in the middle. Undercooking could allow pathogens that might be present to survive.

I am pleased to report that the National Association of School Nurses, who helped us kick off this campaign in Atlanta, will help distribute the post cards through 21,000 school nurses across the Nation. Parents, Bob and Laurie Galler in New York, and Darin and Vicki Detwiler in Seattle, held news events at schools, in their respective cities, announcing the distribution of the post cards, which will include 1.7 million in English and another 250,000 in Spanish.

As you may know, the Gallers lost their three-year old daughter, Lois Joy, to hemolytic uremic syndrome in 1992 and the Detwilers in 1993, lost their two-year old son, Riley, after he contracted HUS when he came into contact with another child infected with *E. coli* 0157:H7. The Gallers and the Detwilers and many other families who have faced this tragedy have been strong advocates for better education to consumers and an improved meat and poultry inspection system, and they are working with us.

As spring and summer approach and people begin cooking hamburgers out on their grills, it is vital to get out the safe food handling and cooking message.

We at USDA are also distributing a food safety package this month. This directive's package with an emphasis on how to protect against 0157:H7 will be sent to over 9,000 fast food restaurants, as well as to national organizations serving the restaurant community. In addition, you might be interested to know that USDA's meat and poultry hotline received more than 130,000 calls in 1993. These calls usually involved questions about how to safely handle, cook and store meat and poultry products.

For 1995, with funds that we are requesting for the fiscal year budget, we will expand our multiagency efforts for pathogen reduc-

tion. At the preharvest end of the system, we will propose a traceback system for determining the sources of microbiological contamination at the farm level. Efforts will also be undertaken to develop educational programs for food producers and handlers to encourage adoption of production practices that limit contamination by pathogens and other hazards.

For the slaughter and the processing segment of this system, inspectors will be trained in the latest food safety techniques; in rapid testing methods that will be developed; and new production practices that may reduce or eliminate contamination. We are also requesting \$7.7 million to hire and to train some additional inspectors.

These efforts will be supported by and coordinated with the Department's research agencies. Consistent with the farm to table approach to reducing pathogens, USDA researchers will devote resources to develop improved production methods and will strive for advances in processing technology, including new meat and poultry inspection tests to identify bacterial levels rapidly and to improve slaughter methods. Newly developed technologies will be demonstrated to producers and to handlers of meat and poultry products through increased food safety education.

In summary, Secretary Espy has pledged that we will have a science-based inspection system that will have a focus on public health; that will have tough enforcement; and that will have improved consumer education, including our safe handling labels. That is the direction that we are going now and it is the direction that we would like to maintain for the future. It is an approach, as I said earlier, goes from the farm to the table, and one that we feel USDA is uniquely qualified to handle.

Thank you, Mr. Chairman, for inviting me here today. I am happy to answer any questions that you or the subcommittee Members might have for me.

Senator KERREY. Thank you very much, Secretary Jensen. Mr. Harman.

STATEMENT OF JOHN HARMAN, DIRECTOR, FOOD AND AGRICULTURE ISSUES, RESOURCES, COMMUNITY, AND ECONOMIC DEVELOPMENT DIVISION, U.S. GENERAL ACCOUNTING OFFICE, WASHINGTON, DC.

Mr. HARMAN. Thank you, Mr. Chairman, Senator Craig. Before I begin and if you think it would be useful, I have two members of my staff that will be available and could come to the table for questioning who have visited, just recently, either visited or contacted some 151 plants. They can provide some insight on what they saw there, if you think that would be useful to the subcommittee.

I am pleased to be here this morning to discuss the recent efforts that you just heard described, many of them, to improve the ability of the Federal food and meat inspection system to prevent food poisonings. As you requested, I will briefly comment on the progress that has been made by FSIS to detect harmful bacteria in meat during slaughter and processing operations. I am summarizing my prepared statements which has been submitted to the subcommittee for the record.

While FSIS had made some changes, the inspection system is only marginally better today at protecting the public from harmful bacteria than it was a year ago or even 87 years ago when it was first put in place. FSIS's recent efforts have neither dealt with the inspection system's inherent weaknesses nor fundamentally changed the system's reliance on sensory inspection methods. These methods cannot identify microbial contamination which is the most serious health risk for meat and poultry.

Although FSIS has known about this problem for 15 years or more, it is years away from an inspection system that can effectively deal with it. These efforts have probably lowered, the ones that FSIS has taken, which by the way, they have spent in the last 2 fiscal years, 1993 and 1994, about \$45 million and about 440 staff years to put together a program of about 81 projects. These efforts have probably lowered the chance that people will become ill from eating meat contaminated with harmful bacteria.

For example, because of its efforts to provide information, as you just heard described, the consumers and retail food establishments may be more aware that raw meat products must be properly handled and cooked to control or kill bacteria. Also, the Agency's more vigorous enforcement of the current sanitation and slaughter processing regulations may indirectly help control microbial pathogens by eliminating some potential sources of contamination.

However, the effectiveness of these actions are uncertain and do not address the current inspection system's limited ability to detect harmful bacteria, to evaluate how serious the problem is and to take corrective action. As we and others have repeatedly stated over the past 15 years, a new scientific risk-based inspection system is needed. It seems as though that is not really a subject to debate. It is really how you do it is more the issue. Such a system would allow FSIS to target its resources toward higher risk meat and poultry products by increasing inspection of these products, developing methods or tools that would help inspectors detect microbial contamination and/or increasing microbial testing of these products.

Well, Mr. Chairman, I have seemed to have lost one page of my summary. There is one final brief comment I would like to make and this really was not in a lot of detail in the prepared statement, and that has to do with the Zero Tolerance Policy which is the issue at the fore here today. That is one of the 81 projects. The stricter procedures required by this policy should logically help reduce the incidence of foodborne illnesses by indirectly reducing some potential sources of microbial contamination.

Senator KERREY. Mr. Harman, particularly for people who might not be familiar with this policy, do you want, just for the record, to define what you see the zero referencing? What is the zero reference?

Mr. HARMAN. It is basically that there will be no fecal contamination present on the meat once it passes through that initial process in the meat slaughter.

Senator KERREY. It does not reference pathogens?

Mr. HARMAN. No, it does not. It does not guarantee at all that you are going to reduce necessarily the microbial load. There are many other sources of microbial contamination. However, from a

logical standpoint, you would have to assume that to the extent you reduce some of that fecal material, you are going to reduce at least the bacteria. Whether you reduce harmful bacteria and the extent you do, is a question. I think that is where the issue of bringing microbial testing into the process is important because you really do not know what enforcing the Zero Tolerance Policy in doing until you have microbial or HACCP-type of system implemented to evaluate it. You could be doing nothing. In fact, you could be causing more of a problem, particularly by using trimming methods; there are those who say that you would increase the contamination.

So that too is a problem. It is not a solution at all. It is a stopgap and it is really not certain that you are going to solve the problem. I think you just caused me to finish my summary. These other sources though that—

Senator KERREY. I have done something useful today.

Mr. HARMAN. Yes, that is right, but these other sources do pose a threat of contamination. To the extent this occurs, the Zero Tolerance Policy could cause a false sense of security and in fact, there is a question, as I said, about whether the method currently being used is spreading it. Now recognizing it is very difficult to argue against the Zero Tolerance Policy, particularly from a consumer perspective, the overriding policy question in our view with this single action may very well be one of the benefits of this effort and just it justify the cost, the economic cost? We do not know the answer to that. As I said earlier, that you really will not know until you start implementing a microbial testing program and a HACCP system into the inspection system.

We will be glad to answer any questions, Mr. Chairman, that you and the Senator may have.

Senator KERREY. Thank you very much. Mr. Boyle.

STATEMENT OF J. PATRICK BOYLE, PRESIDENT AND CEO, AMERICAN MEAT INSTITUTE, ARLINGTON, VIRGINIA

Mr. BOYLE. Thank you, Mr. Chairman, and Senator Craig, good morning. I have submitted a formal statement for the record and would like to summarize it for you today. More than a year has passed since USDA vowed to revolutionize this Nation's antiquated meat and poultry inspection system. During that time, more than 500 million tax dollars have been spent, more than 200 new FSIS inspectors have been hired, and USDA has issued dozens of statements about inspection reform and initiated some 81 individual initiatives.

I am sorry to report that to date the inspection system has changed little in any way that offers greater consumer protection. I would concur with Mr. Harman's assessment from GAO. To my industry, which is dedicated to producing safe food and to modernizing the inspection system, this has truly been a disappointing year.

The meat industry supports the goal of USDA's zero tolerance policy which is intended to control microbial contamination of beef by controlling potential sources of microbial contamination. It is a policy that was designed to achieve visual reduction and elimination of contaminants, a visual reduction, although it was offered

as a pathogen reduction strategy. In effect, zero tolerance has been a physical defect program, and in effect, it has reduced the physical defects on the carcasses in our beef plants. Our carcasses and the coolers today are cleaner, physically, cosmetically cleaner, than they were a year ago. It does not mean that the pathogens though have been reduced and I have some data to share with you on what has happened with the pathogen levels during the past year.

Unfortunately, that visual strategy has in most cases increased, not controlled the contamination. We have data to show that inspection practices over the past year have not improved food safety by lowering microbial contamination of beef. The additional handling, cross contamination with knives, delayed carcass chilling, all associated with USDA's zero tolerance policy, have either had no effect or have actually increased bacteria on beef carcasses. A survey of 15 major beef packing plants over the past year shows that 73 percent of those plants reported an increase in total bacteria counts—73 percent. Another study of 13 beef plants, operating under zero tolerance during the same period shows that 77 percent reported increases in *E. coli* counts on their beef carcasses.

Not only has the current zero tolerance strategy generally not reduced microbial contamination, it has cost the beef industry, producers, packers, and our consumers, an estimated quarter of a billion dollars in the past year. Now I should emphasize for the record that the counts that I am referring to are astonishing low counts, but the counts during the zero tolerance are at a higher level than they were during the preceding year. A quarter of a billion dollars to our industry exceeds our industry's total annual profit margin. Those costs which result from trim loss, increased labor, plant down time and product shrink are being passed forward to consumers and backward to the cattle producer.

Fortunately, we believe there is a better way to remove both the visual and the invisible contaminants from beef carcasses better than the zero tolerance method of hand trimming with a knife. It is utilizing a carcass spray wash, using hot water alone or hot water in combination with an anti-bacterial solution. Researchers have demonstrated that the washing process is actually more effective than knife trimming for cleaning up beef carcasses.

The data that I would like to share with you today has been previously shared with the Department of Agriculture. Mr. Chairman, may I do a show-and-tell?

Senator KERREY. Absolutely.

Mr. BOYLE. The research shows that beef samples that were deliberately contaminated with bacteria and manure had an average of about 6.3 logs of bacteria per square centimeter. Identical samples that were hand-trimmed of visible contamination, in effect utilizing the Department's zero tolerance program—

Senator KERREY. Mr. Boyle, I do not know how the cameras are going to adjust to this. Perhaps Senator Craig can see that from here—I cannot.

Senator CRAIG. Mr. Chairman, I can see it very clearly.

[Laughter.]

Mr. BOYLE. Would you like me to pass this to the table?

Senator KERREY. Actually, it would not upset me terribly if you did pass it up here, but at some point I would not mind actually moving all of you down to this end of the table, so we could have a little closer discussion than we are apt to have with you at a great distance.

Mr. BOYLE. I can empathize with your concern about seeing that. I celebrated my 40th birthday this past week, so I have similar concerns. As I was saying, the research shows that the samples that were deliberately contaminated had an average of about 6.3 logs of bacteria per square centimeter. Identical samples that were hand-trimmed of the visible contamination, in effect, using the Department's zero tolerance requirements, had a 2-log reduction in the bacteria, but samples that were simply washed with a spray of hot water, or treated with ozonated water or a dilute solution of hydrogen peroxide, had a larger reduction in bacteria counts. This reduction represents a 10-fold decrease in the number of bacteria relative to the USDA required trimmed samples and 1,000-fold decrease in the samples that we intentionally inoculated with bacteria.

I have another visual chart I would like to pass to the head of the table, Mr. Chairman. Researchers to date have concluded that washing and spraying alone can effectively remove physical contaminants and can lower the microbial load on beef without increasing the microbial load on adjacent services. That chart, Mr. Chairman, is a summary of the visual reduction that was perceived with the eye, pursuant to a scoring system worked out with the Department of Agriculture. It shows that by washing, you can have a visual reduction in service contaminants, but even more importantly by washing, you can have an actual reduction in the microbial count on the carcasses.

Also Dr. James Marsden of our staff who has worked with the research is available in the hearing room if you have any specific questions about the research that you would like answered.

At this point in time, Mr. Chairman, we are in plants in a commercial setting testing the washing versus the trim and if that in plant research supports and reaffirms what we have already done in the laboratory, then we would urge USDA to move immediately to approve proper carcass washing procedures as an alternative to the hand trimming now required under zero tolerance.

In the interim, meat and poultry inspections in our view are inconsistent throughout the country, and in some cases they are actually, in our view, retaliatory. The industry wants to work with the inspectors in a cooperative way, but in my view the open hostility and retaliatory actions of a small minority of inspectors has undermined the entire inspection system and we believe it must be stopped.

Zero tolerance is just one symptom of an inspection system in need of a dramatic, revolutionary overhaul. Problems associated with this policy have resulted in inconsistent enforcement on the part of inspectors and in some cases blatant inspector retaliation against plants. Neither FSIS nor USDA management has acted to correct these abuses of the system.

For example, one of the Nation's largest, and we believe most progressive beef packing companies recently invited a United

States Senator to tour one of its Midwestern Senator's visit, we believe in response to the tour and the discussion that ensued while the Senator was on-site regarding zero tolerance, the plant has documented a 5-fold increase in inspector-generated down time with no apparent reason, except for the Senator's visit. That plant has watched 1,600 workers stand idle while a single inspector repeatedly slows or stopped the line in the name of zero tolerance.

There are currently 8,600 meat and poultry inspectors working in the field. What does it take to become a meat and poultry inspector? A high school education and a few years working either in a meat or poultry business in any capacity or some related educational courses, such as in biology or animal science. Our members assure me, and it has been my experience, as well, that most of these inspectors are well meaning, but it is inexcusable for an entry level employee with maybe no more than a high school education to idle 1,600 workers for days at a time, cost a company millions of dollars, because that individual inspector at that plant on that day has come up with a new interpretation of a visual, subjective zero tolerance requirement.

In conclusion, we are asking your assistance and the assistance of the full committee to support the accomplishment of three things:

First, we need you to join us in encouraging USDA to adopt a better strategy for enforcing zero tolerance, specifically to allow companies to use carcass spray washes as an alternative to hand trimming, to achieve a safer and cleaner product.

Second, we would like you to join us to urge USDA to take swift and serious actions against inspectors who engage in arbitrary and vindictive activities in the plants. It would be useful for USDA to establish a review system by which it can evaluate the appropriateness of inspector actions in plants relative to public protection.

Finally, we believe all of us must hold USDA accountable for developing the scientific evidence to prove that any new policies, enforcement strategies or initiatives such as zero tolerance do not unintentionally worsen the safety of an already safe food supply. Conversely, we should urge USDA to approve new technologies proven to enhance the safety of the food supply in meat and poultry plants like a HACCP-based system, which the Food and Drug Administration has already promulgated a regulation for the seafood industry and is about to promulgate an advanced notice of proposed rule-making for the other food companies that they regulate.

Preventing foodborne illness is a serious matter. The meat and poultry industry is seriously committed to prevention and is investing millions of dollars in technology, training and research to achieve that end. USDA should show an equally serious commitment by adjusting its enforcement actions to improve food safety.

Thank you, Mr. Chairman.

Senator KERREY. Thank you, Mr. Boyle, Ms. Foreman.

STATEMENT OF CAROL TUCKER FOREMAN, COORDINATOR, SAFE FOOD COALITION, AND PRESIDENT, FOREMAN AND HEIDERPRIEM, INC., WASHINGTON, DC.

Ms. FOREMAN. Thank you. Once again if I could have my full statement inserted in the record, I'll summarize.

Senator KERREY. Without objection, so ordered.

Ms. FOREMAN. I think it is probably worth noting that foodborne illness is a serious problem in this country. Representatives of our Government and of the food industry like to brag that we have the safest food supply in the world. The Department of Agriculture spends \$600 million of our tax dollars each year to inspect meat and poultry. Every package of meat and poultry carries the imprimatur of our Government with a stamp that says either inspected and approved, USDA or inspected for wholesomeness.

I think, we believe that Government and industry are promising more than they are delivering. Each year foodborne disease kills about 9,000 Americans and makes between 6.5 and 80 million of us sick, according to the Centers for Disease Control. USDA's own Economic Research Service says foodborne illness costs the American people between \$5 and \$6 billion a year with about half of that resulting from meat and poultry products. When you add the cost of inspection to the cost of these failures, the Nation is paying a very high toll for a program that is not very successful in meeting its goals.

Meat and poultry inspection, I think, almost everybody here at the table agrees is archaic and frequently ineffectual. As the Caucasians approach the millennium, the inspection system stuck somewhere back at the half past the century. After the *E. coli* outbreak on the West Coast in early 1993, Secretary of Agriculture Espy pledged to improve the system. One of these first steps, because he had to take some in a hurry, was to pledge that USDA would start to enforce the existing regulation, the existing policy of the Department, which was a zero tolerance for fecal contamination of beef.

We endorsed that action then and we do now. Zero tolerance simply means that beef contaminated with feces, ingesta or milk cannot be processed. The contaminated meat has to be cut away. Feces, ingesta and milk are commonly the carriers of pathogenic bacteria that make people ill. It is not impossible to find sterile feces, but I am not going to bet my health next week on it.

Whereas we can be pretty sure that visible fecal contamination reflects the presence of pathogenic bacteria, as Mr. Harman pointed out, the absence of visible feces on meat does not guarantee that there are no bacteria present. Zero tolerance is a crude tool, but it seems to be the best one USDA has available today. The Department and the industry have avoided for years developing the fast, effective test that can detect harmful bacteria, and they have avoided setting limits on the amount of disease-causing bacteria that can be present on raw meat and poultry.

If anything comes out of this hearing today, it ought to be urging the Department to move forward much faster on those goals. At least until a better system is developed, peer reviewed, tested in a wide variety of plant environments and found to be effective in keeping pathogenic bacteria below a critical level, the Safe Food Coalition supports the continuation of the policy for zero tolerance for fecal contamination. The Cattlemen's Association and the Meat Institute argue that the application of zero tolerance policy does not reduce or may actually increase bacteria levels. Those assertions seem to be supported only by anecdotal evidence.

We would hate to see USDA make a policy decision without having these tests reported today independently verified and pilot tested in a wide variety of plants under different conditions. The Department should not change its existing policy without more proof than is presently available.

Industry trade associations argue that high pressure washing is preferable to hand trimming. Again, the data do not, at this point, warrant a change in the policy. There must be further independent testing. It is my understanding, from Acting Assistant Secretary Jensen's testimony, that the Department is in fact working with the industry and expects the results from those tests to be submitted. We are not sure why the Department is being criticized when the tests that the studies that the Department has out have not been submitted to the Department.

The industry also charges that zero tolerance policy is being applied unevenly and we have heard similar charges and we think that that is a very serious problem. We have heard that it is being applied so vigorously in some places that plants have been forced to slow down severely. We have heard that in other places it seems to just not be in effect at all. The Department simply has to investigate these charges and respond and assure a uniform enforcement.

Now it is clear that the Zero Tolerance Policy costs both cattlemen and processors money, and clearly the Safe Food Coalition does not believe that either should be penalized unnecessarily or inequitably. However, the cost of trimming is less than the cost to consumers of foodborne illness and the cost of trimming has got to be less than the cost of a further loss of public confidence in the efficacy of the system and the wholesomeness of our meat supply, especially right here at the beginning of the cookout season. Surely nobody wants to send the message that industry or the Department of Agriculture endorses passing fecal contamination of beef through the process.

Now the goal of meat and poultry inspection is to reduce the causes of foodborne illness. I think there is fair agreement around the table that there is a better way to achieve this goal. Industry and the Department should strive to reduce the presence of pathogenic bacteria in meat and poultry below a level that is likely to make humans ill. We believe that the best way to achieve this goal is:

First, to institute a hazard analysis and critical control point system for meat and poultry inspection.

Second, to require that plants using HACCP sample for pathogenic bacteria, both at critical control points and at the end of the production line, in order to verify that the HACCP program is working as intended.

Third, establish maximum acceptable levels of pathogenic bacteria for raw meat and poultry products. The HACCP program in each plant just has to be capable of regularly producing product that falls below those maximum levels. The steps will not eliminate all pathogens but together with USDA's public education program, it surely should help to reduce foodborne illness.

We continue to believe that the present system in which Federal inspection is divided among a number of agencies waste precious

resources, and in the words of the GAO, create serious gaps and overlaps in inspection. We continue to support legislation by the Congress or action by the Executive Branch that would combine meat and poultry inspection and other food inspection programs together in one public health agency. We think in that way we could truly extend inspection and food safety from the farm gate to the consumer's plate.

Thank you.

Senator KERREY. Mr. Wilson.

STATEMENT OF GARY WILSON, DIRECTOR, ANIMAL HEALTH/INSPECTION AND RESEARCH COMMITTEES, NATIONAL CATTLEMEN'S ASSOCIATION, WASHINGTON, DC.

Mr. WILSON. Good morning. My name is Gary Wilson. I am Director of the National Cattlemen's Association, Research and Education Committees, Animal Health and Inspection. Particularly want to thank this subcommittee for giving us the opportunity to participate in today's hearing. We also commend the subcommittee in conducting these hearings to address improvements to the Nation's meat and poultry inspection system.

Let me make it very clear that NCA believes it is imperative for consumers and the beef industry that the meat and poultry inspection system be effective and above reproach. Public safety concerning our products is of paramount importance. In the production process, cattlemen can invest up to 5 years getting an animal to market. Beyond that point, we have no control on what is done with or to our product. Any negative concerns relating to inspection inadequacies impact consumer buying habits which in turn negatively impacts our market values.

NCA supports the establishment of a meat and poultry inspection system that is based on risk assessments, scientific analysis, and implemented in conjunction with hazardous analysis and critical control points. Visits with Congressional leaders and staff have told us that the current meat and poultry inspection acts are written broadly enough to allow USDA to upgrade, improve, modernize the inspection system. Subsequent visits with the Department at USDA reveal an opinion that the law does not allow for certain improvements or changes in the inspection procedures or adoption of the technology and they cite a need for change in the law.

Packing and processing companies can provide documentation indicating improved technology has not been implemented due to restrictions in the rules and regulations and laws governing meat inspection. In fact, a good example is USDA's re-issuance of the zero tolerance rule and the subsequent hand-trimming requirement for removal of physical contaminants.

Taunted by USDA as a crack down on industry to help combat physical and microbiological contamination has only filled the consumer with false hope. When first initiated last year, industry met with the Department to discuss the opportunity for instilling a wash spray technology that had been successfully developed and implemented as a component to streamline inspection pilot tests, and technology already approved for slaughtering poultry. We were told that we needed to conduct additional research. We asked for research supporting the current trim only requirement.

We were not surprised to learn that no research exists to support the current rule.

A recently completed research project known as the wash/trim study, that Mr. Boyle fully outlined, has concluded that the high pressure, 300-pound pressure, hot water wash of beef carcasses, followed by a bactericidal rinse, can be effective in removing physical contaminants and far superior in reducing pathogens and contamination on carcasses.

While we all agree and recognize that physical contaminants should be removed, let us also recognize the fact that additional handling of carcasses by inspectors and plant employees, actually contribute to microbiological contamination. I want to emphasize that the zero tolerance initiative is a fallacy. For a year it has caused cattlemen over \$5 per head for every animal slaughtered with no improvement in food safety. This is a classic example of the Department trying to use 1906 antiquated regulations and methods in dealing with today's problems.

Phase three of the project, as Mr. Boyle outlined, the commercial application is currently underway, and we hope to have the results by July. Our concern is that this research review will be held up by government bureaucracy, inspectors union diatribe on efficacy, and activists innuendo to stall approval and use of this equipment, as has occurred in recent years with other technology and initiatives. We only need to look at the recent HACCP round table.

Incorporating HACCP principles into the inspection system was discussed by USDA's Meat Inspection Advisory Council 4 years ago. Yet, the bureaucratic system in place today, along with political interruptions that influence FSIS operation and vacancy in the administrator's office, indicates that the system we have is not capable of productive change within itself. There will need to be a complete paradigm shift in attitude and understanding from the Secretary of Agriculture's office to the inspector in the plant.

It took 6 months to organize and conduct the now very infamous HACCP round table. Now, we are told, it will be another 6 months before release of the proposed rule. Who knows how long it will take to reach a final rule and implementation of HACCP.

Producers are tired of having the integrity of our products questioned and held up for public ridicule while bureaucrats and activists quibble over round tables, job security, the additional call for pilot testing of known research results. I might remind you that the streamline inspection pilot test lasted 6 years. Quite frankly, consumers and producers cannot afford to wait for more pilot testing so that Carol feels good.

Producers in the packing processing industry already spend over a billion dollars annually for product safety and quality control. This investment can complement a HACCP-based system. New Government regulations should capitalize on voluntary industry initiatives. As we move forward on inspection reform, we should also take advantage of the opportunity to modernize and harmonize existing meat and poultry legislation and regulations. Consumers in industry can no longer afford to allow antiquated laws or regulations hold back a modern, science-based inspection system.

Mr. Chairman, the rest of my testimony outlines some of the initiatives that the beef industry has conducted over recent years,

particularly in support of research supporting 0157:H7 and outlines other positions on meat inspection reform. I would ask that the rest of our text be submitted for the full record. I also again would like to thank this subcommittee for the opportunity to participate and commend you, Senator Kerrey, for your leadership in conducting these hearings.

Senator KERREY. Thank you, Mr. Wilson. I do not why you pulled your punches like you did, but I appreciate your statement.

[Laughter.]

Senator KERREY. At this time, I would appreciate it if the additional GAO staff would come to the table. I do not know if any USDA folks want to come up. I would really just like to have a conversation at this point and talk about the current policy. I do not know how Senator Craig feels about it, but I suspect it is the same. We do not want to send out a message, and I intended not to send out a message that inspectors ought to back off on the objective of eliminating fecal contamination from carcasses. To me zero tolerance is a worthwhile objective and I do not want to run the risk of leaving this hearing room with a message going out to folks that Kerrey held this hearing because he wanted to back off and get the inspectors to back off. I do think that there has been some punitive action out there and I am concerned about some of the reaction to our interest in this issue.

There is no question that all of us, as I hear the witnesses' testimony, have a shared sense of purpose. The purpose is to provide the American consumer with the safest possible food that we can, and to use the most available technology, and to use good science as well to get the job done. My own feeling, and I shared this with Secretary Jensen in a conversation that we had last week, my own feeling is that we are going to need a significant cultural change to say the least inside of the inspection community.

In fact, the suggestion that I made in the conversation was that the term "inspector" be dropped and they ought to be converted into health specialists and they ought to come into plants and say, if you share our goal of providing safe food, then we are prepared to be a partner. We are prepared to work with you and bring technological ideas. We are prepared to bring resources. We not only want to help, but we have got resources at State Departments of Health. We have got resources at State Departments of Agriculture. We are prepared to help. If you want to provide safe food leaving the plant, we are your best friend. If you do not, we will be your worst nightmare.

Unfortunately, as I see it, we are trying to inspect our way to a solution and we have created an environment of confrontation that frankly I do not think gets the job done. I think if we continue in an environment of confrontation, we are going to have a lose-lose situation. Taxpayers are going to lose; consumers are going to lose; and in the end, the economy is going to lose because we are going to have people that are going to be standing around idle and not working, while we settle whatever conflicts we have got. That clearly has happened in plants in Nebraska. If it has happened as a consequence of the need to change a system, improve consumer safety, I am not going to interfere with that.

If it is unclear that you are producing any benefit from that kind of an operation, then I am going to interfere with it. Anyway, Senator Craig, I do not know if you wanted to bat at anything.

Senator CRAIG. I do. I am very frustrated when the marginal gain that might have been made is costing the producers so much. I will be very straightforward about that. I think the producer is willing to pay more if the gain is substantially significant. I think it is entirely wrong to suggest, and I made notes here, that this hearing would be sending any message that somebody is accepting contamination. That just ain't so. Nobody is accepting it.

What we are trying to drive toward is an effective process and I thought this was extremely interesting, whether it be preliminary studies or not, I am not sure we can walk away from those statistics and suggest that we are going to just keep pouring money into a process that is costing more and more. As the Chairman says, slowing plants down, when we ought to be doing aggressive experimentation across the board.

Now we have had two hearings. It says increased trimming, increased handling creates increased contamination across the board. Somehow that does not make sense that we are going to keep driving at that without doing an about face turn. We are going to wait till December. We will have gone through another season. We hope no one will have contracted a problem. I am extremely pleased to see that we are willing to say that the consumer has a responsibility to.

I think, Ms. Jensen, your comments about increased education are extremely valuable. We want to see that happen. The consumer has to be knowledgeable in the preparation of food. It cannot all be done for them. It is not a zero some game or a zero safe world and we know that. That has got to be part of it.

I am terribly frustrated as we march down the line here and we are spending a lot of money and the industry is paying out more money—a quarter of a billion dollars and we are on the margin of being marginally improved. When GAO says, maybe, but that was kind of a maybe. I don't see that that was an emphatic yes, the world is better. That is a heck of investment to be only marginally improved when it appears that there are significant findings, that we ought to push to the forefront aggressively and rapidly to move the industry the way it appears to want to move.

I think we are all terribly frustrated, Mr. Chairman, when we just accept the idea that it is going to take 2 or 3 years to make a decision in this city. It should not take that long when scientific evidence is rapidly accumulating out there that says we can move in much shorter time to improve the environment in which food is being brought to the consumer.

Senator KERREY. Ms. Jensen, can I ask you, do you think the current law gives the USDA the statutory authority to test for contaminants, pathogen contaminants and withhold product from the market based upon that data?

Ms. JENSEN. As for the testing of contaminants, I am not aware of situations where we will need significant law change, but on the recall situation and the definition of adulteration, there are some issues there which do need to be addressed by law. We working on

that legislation; we have a final package that we are discussing with the Secretary; and hope to have over here very shortly.

Senator KERREY. So you are saying that you do not have the statutory authority to test for pathogens and withhold product based upon those microbiological tests?

Ms. JENSEN. I am saying that we do have most of the authority to test, but I am saying the withholding and recall part is where we are needing to have some more authority under law.

Senator KERREY. Mr. Boyle?

Mr. BOYLE. Mr. Chairman, I am a lawyer by training, but a non-practicing one, so you have to factor that into my analysis of the legislation the Department operates under. In terms of recall authority, the Acting Assistant Secretary is right, they do not have recall authority, nor does the Food and Drug Administration. FSIS has the authority to withhold product from the marketplace or to remove it. Or to withhold product from the marketplace in the plants. They do so when the product does not meet standards that they have set, such as zero tolerance.

As you are well aware, there are coolers all over this country that are being locked up, tagged up until the product comes into compliance with the requirement and the product is not going to interstate commerce until then. When product may have gone out of the plant and into the marketplace where recall may be in order, they do not have that authority.

In every instance that I am aware of over the last two decades, every time FSIS has informed a plant that product got through the plant and the Inspection Service and is now somewhere in interstate commerce, that plant is given the choice of having FSIS issue a press release telling consumers that the product is adulterated or the plant has the opportunity on its own to voluntarily recall the product.

In every case, the company has voluntarily recalled the product. It is a very effective enforcement tool. I am not quite sure the Department needs the recall authority, because they never had to get to that point because companies always voluntarily recall their product.

Senator KERREY. How about withhold authority? Do you feel like you have the authority to withhold, based upon pathogen count?

Ms. JENSEN. I would like to ask Craig Reed who is our Deputy Administrator of Inspection Operations to tell you the legalities.

Senator KERREY. For the record, Craig's head was shaking no.

Dr. REED. We have not set a level in raw product for pathogens to either pass/fail. We have that on cooked product, but we do not have it on raw product.

Senator KERREY. In your microbiological baseline study, can you tell me why you chose fed cattle? I mean why did you choose not to use cows?

Dr. REED. In fact, we did at a later date. We started with fed cattle.

Senator KERREY. You started with fed steers and heifers?

Dr. REED. We started with fed steers and heifers. We are currently doing cows and bulls and we have done a ground beef study also. So, there have been a number of studies.

Senator KERREY. Let me ask Mr. Boyle then. How do you feel about using the pathogen count as the target, as opposed to using a visual sighting of something that you cannot see?

Mr. BOYLE. The visual sighting of something you cannot see is a particularly in effective approach. Utilizing microbial standards for guidelines is being done today, pursuant to USDA regulations. For example, on products where industry has the ability to eliminate bacteria, such as on ready-to-eat products, hot dogs, baloney, on canned meat products, on precooked roast beef where we have the technological capability to meet a zero tolerance, which is the standard that has been set for pathogens in those products, Mr. Chairman, we do live with an accept or reject basis pursuant to our ability to meet that tolerance level, that zero tolerance level. If we do not, the Department withholds the product.

Now in terms of raw products, we do not have a microbial standard on an accept or reject basis, and there are a lot of reasons for that. First, one is not sure, the experts are not sure what is an infectious dose. What would even be an appropriate level to set? A 100,000 plate count, for example, and if your product is at 99,000 plate count it is OK, but if it is at 101,000 plate count, it is not; but it gets shut out of interstate commerce. There is no medical or public health basis for such an arbitrary establishment of a standard.

The reality is though, if the product is prepared and handled properly, whether that plate count is about 100,000 or below 100,000, it becomes safe for human consumption. However, that does not mean that microbial guidelines do not have a place in the processing of food. They do. They are a very effective indicator of whether or not our processes, our HACCP-based process control systems are working. If we fall below those targets, that means our system is in compliance with our standards. If we fall outside it, we then have to go back and adjust the system and make sure we get within the tolerance.

USDA has adopted that kind of microbial guideline for the meat industry to supply ground beef to the school lunch program. They implemented that with our support 2 years ago and if you meet the guidelines on ground beef, your product is acceptable. If you do not, you have a window of time to get within that tolerance. Failing that, you no longer are supply the product to the school lunch program. Guidelines, microbial testing, makes sense on both raw and cooked products, but they have a different application.

Senator KERREY. Ms. Foreman, did you want to comment on that?

Ms. FOREMAN. Sure do. It seems to me that everybody is dancing around this in order to avoid asking the real question which is, does USDA right now have the power, the legal authority, to set standards for acceptable levels of bacteria in raw meat and poultry? I am not asking if they have the scientific capacity, I am asking if they have the legal authority? We have, from former General Counsel of the Department of Agriculture, a letter saying they sure do.

Senator KERREY. I think Ms. Jensen just said that she does. Her answer was yes.

Ms. FOREMAN. I did not hear that.

Senator KERREY. She answered yes that they do have the legal authority. The question was on withholding, whether or not they have the legal authority to withhold.

Ms. FOREMAN. Somebody would argue that the Department, having set a standard that says, above this level, the product is contaminated; that the Department does not have the legal authority then to prevent that from going forward. I do not think I accept that and I do not think any court in the land would accept that the Department does not have the authority to stop this shipment of a product it has said is contaminated.

Senator KERREY. Ms. Jensen?

Ms. JENSEN. I should disclose also that I am a lawyer and I think that where a problem comes in is deciding what the legal term of adulteration is all about and what the authority is that comes with that once adulteration is found. We consult with General Counsel who tells us that now what we should do is think in terms of recall authority and the definition of adulteration and to include that kind of contamination in that word. So that is what we are developing in legislation so that we will have the authority to recall under those circumstances.

Ms. FOREMAN. But the authority to withhold shipment, to stop the shipment. That is not recall—that is to stop the shipment.

Ms. JENSEN. No, and we do have the authority to withhold. The problem with much of this is again dealing with the science. We do not often know whether something is contaminated until we have gone through some scientific testing, and by then product can be out in the stream of commerce. We think it is very important that we have that authority then to reach out if we find that contamination and recall that product.

Ms. FOREMAN. Could I point out, Senator, that in 1985, under contract from the Department of Agriculture, the National Academy of Sciences said that the Department should already by then have had both data about infectious dose for various pathogens and rapid test methods. We are not going to have them in 1995.

Mr. ZADJURA. This is getting very confusing.

Senator KERREY. Just for the record, you need to identify yourself, Sir.

Mr. ZADJURA. Ed Zadjura from GAO, and I am not a lawyer. I do not think the real issue here is whether or not they can set standards or whether or not they can withhold the product. I think clearly, they are saying they can set a standards and they can clearly withhold the products since USDA, unlike FDA preapproves product. The product does not go to the market unless USDA says it is OK. It is a slightly different question about recall authority.

The real problem here is that even they were to set standards, you cannot set standards that would apply to each and every piece of meat, each and every carcass, each and every piece of poultry. Whether or not the science is there to set the standards or not, the test methods are not there. It would be too costly to test every single product, which is where the real discussion of standard setting for microbial contamination gets back to, is whether or not you are going to have a HACCP system and whether or not you are going to use those standards to monitor the overall system which would

say essentially on average this plant day-after-day and hour-after-hour based on this testing is producing clean product.

You cannot do it in any way, shape or form because of technology limitations and cost limitations on a piece-by-piece basis. You cannot use microbial standards in testing for a pass/fail on a chicken wing, if you will, or a steak.

Senator CRAIG. So you are talking process, not individual specific, but a process that we all can agree produces continually day-after-day?

Mr. ZADJURA. That is correct, Senator.

Senator CRAIG. A product.

Mr. ZADJURA. That is correct. As every single party that has testified today has said and we are more than grateful to hear it, since several years ago we issued a report saying this, that we should go to a modern, scientific, risk-based system using the HACCP concept.

Senator KERREY. How do I go to a modern, scientific risk-based system using the HACCP concept with individuals who are trained in the field to basically go out and find defects in the operation and issue penalties accordingly? I mean, I do not have an operation out there in the field that, it seems to me, enables me to carry out the thing that you just described we need to do.

Mr. ZADJURA. We have advocated for several years now in numerous reports and testimonies that we need fundamental, basic changes to even the law. The law right now, even if you put a HACCP system, it is going to be layered on top of the carcass-by-carcass inspection requirement. It is only going to cost more money to keep what we have said is an ineffective and inefficient system in place. We need to revamp the current system and change the laws, not simply to try and put something on top of it, Senator.

Senator KERREY. The question that I have is I can change the law but I must be changing the law for a purpose. It seems to me that the purpose that ought to be in place out there, the system that ought to be in place out there is an environment where I have USDA specialists coming into a plant saying we have expertise and capacity to help you produce a high quality, safe product. If you are prepared to participate in that goal, we are your best friend. We have resources and capacity to help you, and perhaps you have some things that you have discovered on the job that works better, and we are prepared to cooperate with you to get that done.

In other words, I need to decide what kind of operation I want out there in the field before I write the law. Do I not?

Mr. HARMAN. That is absolutely correct, Senator. I could not agree with you more, everything you said. The question you are raising is how do we move from one system to another one which involves major, major paradigm shifts and changes in attitude and responsibilities of people that are currently involved in the current system and where you will have perceived the winners and losers, as a result of this change. So it is what is your strategy to achieve that change?

We would argue that it is not something that you are going to do over night with legislation. It is something you have to get the stakeholders involved in. It is something that you have to have a strategy for, just as a strategy for moving forward to that system

from a technological standpoint. We also know from visiting these plants, that there are plants out there that are currently using microbial testing in their process. Also, there is an opportunity to take advantage of what they are learning from that. So there is an opportunity to start moving to that, even within the current system, and then over a period of time, start making changes and moving out of the current system into a new system.

Ed is absolutely right. It is going to take legislative change, but you have to know where you are going before you can implement that legislation. You have to have a strategy for implementing it. Otherwise, we are going to be back to where we were in 1986 when we tried to implement something a little bit similar to this with discretionary inspection and it did not work.

Senator KERREY. Mr. Wilson or Mr. Boyle, either one?

Mr. WILSON. Senator Kerrey, we have had these discussions before. Quite frankly a year, a year and a half ago, right after the outbreak. There was an outline by the Department of Track I and Track II. Track I was to initiate research that we could do immediately and make changes that we could do immediately under existing rules and regulations. Track II was longer term, scientific approach and methodologies to convert from the current system to a science-based system. Now for some reason, we have not heard much about Track I and Track II since February or March and I guess I would like to know what is the status of Track I and Track II. Because I thought we had a plan that we were following that accommodates many of Mr. Harman's suggestions or approach to this process.

Ms. FOREMAN. Why do you not ask Mr. Harman if he thinks Track I and Track II address his concerns.

Mr. HARMAN. Do you want me to answer that, Senator? No, we do not think it has.

Senator KERREY. Mr. Harman, do you think Track I and Track II—

Mr. HARMAN. Track I was basically changes you will make to the current system that will result in some improvements to the current system. Track II was a major revamping of proposals to have major revamping of the system to go towards more a risk-based system. It is one thing to put things on paper. It is another thing to implement. I think that we would say looking at the information that was put out and the plans, that it headed in the direction, and I listened to Assistant Secretary and I can agree with much of what she is saying. "The big question is, how we get there, and how much time do we have?"

Senator KERREY. Let us walk through the current issue then and see if it is possible to discover where there is some common ground, if there is any, which I think there is. Let us deal with the current policy of accomplishing zero tolerance through trim. That is the current policy. The current policy is and I hear all the way around the table agreement that zero tolerance needs to be enforced. That we need to enforce a zero tolerance policy meaning that we should not tolerate fecal matter, ingesta or milk on the carcass. Is there any disagreement with that as an objective? Do we all basically—I mean do AMI and the Cattlemen and Ms. Foreman and others say, no ingesta, fecal matter or milk on the carcass?

Ms. FOREMAN. I hate to complicate it because certainly I agree with that, but the day may come——

Senator KERREY. Well then do not complicate it.

[Laughter.]

Ms. FOREMAN. That is what I am here to do. You have got to take into consideration that some day we may have enough information to know that, in fact, there is a certain amount of fecal matter on the carcass and it does not make any difference at the end of the line in the finished product. So it is important right now, because it is what we have got, but in the long term, there may be that much that does not make any difference.

Senator KERREY. With great respect, Carol, we put a trim policy in place with no scientific analysis. Secretary Espy did not say, I have to have a study of this trim to make sure it gets rid of *E. coli* before I put the trim policy in place. We went out there and put it in place. Is that right or wrong?

Ms. FOREMAN. It was in place beforehand.

Senator KERREY. Did Texas A&M do a study of the trim?

Ms. JENSEN. Mr. Chairman, the study that I referenced as being conducted by Texas A&M currently, that we are expecting the results from in December, does include some testing on the trimming aspect also.

Senator KERREY. What I am saying, Ms. Jensen, is that the trim policy was put in place as a consequence, but I think of understandable concern about fecal matter being allowed. It was not put in place after a study had been done. In other words, we did not say——

Ms. FOREMAN. Sir, it was put in place before the 1993 outbreak. It was part of the manufacturing procedures that the Department imposed for physical defects. It is just a——

Senator KERREY. The purpose of this hearing is not to come and say, let us stop the trim. I am trying to find a satisfactory, scientific based system that accomplishes the objective of zero tolerance.

Ms. FOREMAN. I am agreeing with you by saying that some day we may know there is a certain amount that does not make any difference. We just do not know that right now.

Mr. BOYLE. Just to clarify the record, the Department prior to last year, did have a physical defect requirement in place that addressed fecal matter, ingesta and other contaminants on the service of the carcass. They had, pursuant to that requirement, a minimum standard that anything above a certain minimum size had to be trimmed off; but that specks so small, minute—perhaps, Carol, based upon the rationale—that it did not matter at the end of the day going from a 1,200 pound carcass to a 3-ounce steak.

What happened early last year is that we went from a physical defect standard, with tolerances that were understood uniformly, throughout the system, and applied, uniformly, in every plant, to a zero tolerance which meant that any speck, no matter how small, how minute, how many flashlights and inspectors and hours in a cooler going row-by-row, chain-by-chain, it took you to find a speck, and lock up a whole cooler, is how that standard was changed. That is the application today—zero tolerance—no matter how small. It was done without any scientific data to support it and it

was done, we think, misleadingly under a pathogen reduction strategy. It has nothing to do with reducing pathogens. It has to do with cleaning the physical characteristics of the carcasses.

Senator KERREY. The Chairman of the subcommittee is here. He has to go back to resolve health care on the Finance Committee, so I am going to let him take as much time as he would like and save my efforts.

STATEMENT OF HON. THOMAS A. DASCHLE, A U.S. SENATOR FROM SOUTH DAKOTA

Senator DASCHLE. Senator Kerrey, you have just done an excellent job of again assembling a group of witnesses that probably know more about this issue than anybody else in the country. I welcome all of you and appreciate again your contribution to this ongoing record that we are trying to develop on this policy.

I would like to announce that we would like to do another hearing some time in June, preferably before the Fourth of July, for the sole purpose of bringing the Department of Agriculture here to give us their plan and to lay out in detail what it is you intend to do. If it is additional legislation or additional authorization you need, we need to get to work on it. We do not have a lot of time. I am becoming increasingly concerned about this.

Senator Kerrey's hearing today has allowed us to move the record forward even more and I appreciate very much his leadership and contribution in that regard. No one on the subcommittee, or on the full committee for that matter, has a greater interest in this issue than he does. So I appreciate the excellent testimony and the good exchange that, I hear, is already underway here. I apologize for my absence. I have to be over in the Finance Committee on an important meeting we are holding there. I would like very much to reassemble at some point in the not too distant future for, as I said, the purpose of bringing the Department of Agriculture back to discuss more specifically their intentions.

I have a statement I would like to submit for the record too, if I could.

Senator KERREY. Without objection.

Senator DASCHLE. Thank you.

Senator KERREY. Thank you very much, Senator.

[Testimony resumes on page 162.]

[The prepared statement of Senator Daschle follows:]

STATEMENT OF SENATOR TOM DASCHLE

Today's hearing on the Zero Tolerance Policy is a continuation of this subcommittee's efforts to monitor our Nation's meat and poultry inspection system. I commend my colleague, Senator Kerrey, for agreeing to chair this hearing.

The safety of our Nation's food supply continues to be a matter of utmost concern to consumers, producers, and industry alike. Everyone has a stake in this issue, and everyone wants to see reform. Secretary Espy initiated the reform process almost as soon as he took office, by proposing a comprehensive list of improvements to be made in the aftermath of last year's *E. coli* outbreak in the Northwest. Although progress has been made, there seems to be near unanimous agreement that much more needs to be done.

The Senate Agriculture Committee took a significant step toward reform in March when we included a provision for an independent food safety agency within USDA in our bill to reorganize the Department. The new Food Safety Service will provide the framework within which reforms to the inspection system can be implemented.

However, make no mistake, this organizational change, by itself, will do little to improve the current situation unless the Department puts its plans for reform into action.

There is nearly universal consensus that the current inspection system must change, and change soon, to keep up with the scientific knowledge and technological advances that have occurred since it was first designed. Beyond this consensus, however, there is a great deal of disagreement on the types of reforms that are needed.

One of the reform policies that has generated diametrically-opposed reactions is the zero tolerance rule. This policy requires mandatory trimming of fecal and milk contamination on beef carcasses. Secretary Espy directed strict enforcement of the Zero Tolerance Policy in February 1993, in response to the *E. coli* 0157 outbreak.

Advocates of zero tolerance contend that trimming is the only sure way to remove contamination, and are concerned that enforcement of the policy is too lax.

Opponents, on the other hand, contend that trimming may actually spread contamination because of the increased handling of the meat, and that carcass washes and sprays are more effective than trimming. Some have criticized that the enforcement of zero tolerance is unnecessarily strict, to the point of being abusive.

While resolving these issues, we must not lose sight of the ultimate goal: a safer meat and poultry supply. I hope that today's hearing will serve to shed some light on these points of controversy. We need to know what all the available scientific evidence tells us about the questions that have been raised regarding the Zero Tolerance Policy. We also need to find out where the gaps in our scientific knowledge remain, and complete the necessary research as expeditiously as possible to provide conclusive, scientifically-valid resolution to these issues.

This subcommittee intends to conduct another hearing in June to examine the Administration's package of legislative reforms related to meat and poultry safety, as well as my own legislative proposals, which will include provisions for traceback and recall authority and improvements to the import inspection system. I have been told that the Department's proposal will be released soon, and I look forward to working with Secretary Espy and Assistant Secretary Jensen in this regard.

Senator KERREY. Let me just read the March 1993 announcement that Mr. W.S. Horn, the Deputy Administrator of Inspection Operations sent out to all the inspectors in charge and plant operators for beef slaughter and boning plants, March 2, 1993. This is the reference that I was making earlier to the move, and whether any kind of study was done prior to making the move.

It describes in a single paragraph the urgency of the need to act as a consequence of *E. coli* problems. It said "Effective immediately (1) all fecal, ingesta, and milk contamination from any source must be trimmed prior to any washing of the carcass; (2) any and all acceptable quality level standards for feces and ingesta or boneless beef are suspended and a zero tolerance for feces and ingesta is to be enforced; (3) the IIC's—which are the Inspectors in Charge—must immediately notify plant management of these standards and our strict adherence to them. Inspection personnel will closely monitor slaughter and processing operations to be sure the plants have control of their production procedures."

Again, I say again for emphasis, the purpose of this hearing is not to send a message out to inspectors that they are to back off, unless there is punitive action being taken as a consequence of disagreement with their policy which I consider to be intolerable and unacceptable. If that is going on out there, as a consequence. So there can be no mistake about it, the Midwestern Senator referred to earlier was me.

The 1,600 human beings working in a factory, supporting families, have their livelihoods at stake out there. So if inspectors went in there as a consequence of my visit and questions that I raised about zero tolerance, if they went in afterwards with a 5-fold increase in inspection activity in that plant, it is completely unac-

ceptable, and disciplinary action should be taken. That is not inconsistent with saying that I do not want to send a message that inspectors should back off of the goal of trying to make sure that we give the consumers safer food than they have got right now.

It is clear going around the table that our policies need to be changed. We need to change the policy. The question that I was trying to get at with a discussion—and I do not think actually, Carol, that you complicated it—that is, how do we evaluate alternative procedures to get that done? How do we get that evaluated in a manner that allows us to use scientific data?

I believe you used the anecdotal reference. Mr. Boyle was saying that they have got reference data at Colorado. These two charts, I think, were from a Colorado State evaluation. I do not know if those are independent. I do not know how USDA regards these kinds of evaluations.

Ms. JENSEN. Mr. Chairman, we have been working with AMI and the Cattlemen. As the protocol were developed for this particular work at Colorado State, USDA was there working and participating. We are very supportive of what is happening here. You mentioned Phase III which is where the study is now. We are working with these groups and watching to see what the results will be in the same way that they are. We are very anxious to get that and are hopeful to use that data as we make decisions at USDA.

So there is no conflict here. It surprises me when it is presented in a way that appears that, in fact, USDA is feeling some conflict or some resistance to this scientific data. In fact, we are very, very pleased at what is going on here and will use this data, hopefully to make our decisions. We are also looking forward to the Texas A&M study, and as Acting Assistant Secretary, I sure hope that it does not take 2 or 3 years after getting data to make something happen. I make a commitment to you here this morning that when we get this data, we will review it. We have every reason to expect that it will be good, scientific data and we will act.

Ms. FOREMAN. May I comment?

Senator KERREY. Yes.

Ms. FOREMAN. We want the Department to be more science driven. You sure do have agreement around the table about that. We have some concerns about the way science has been done at the Department in the past as perhaps cozy relationship and not always a very detailed study. In this case, there were 1,359 beef carcasses in a 300 per hour slaughter line. It was a high speed steer heifer line. I would like to be assured that before anybody went forward with this study, they would have some additional data to indicate that the carcass spray is as effective in older plants that run more slowly, in plants that deal with call cows, and a whole range of other plants.

My concern is when the industry comes to the table and describes a limited study as being the basis for making a major change. I agree with you, there are no data to back up hand trimming. It is a gross, crude tool, but I get very troubled when you come to the table, and USDA has done this for years, and have said we have got a study. Then I go and read this study and the study is a lot less persuasive to me and sometimes misdescribed. Yet, in this case, it is a rapid, steer heifer operation, one plant.

Mr. BOYLE. Mr. Chairman, there is always a risk when you come forward with any study that tries to shed some scientific light on a situation. The risk is greater when you come forward to a hearing that was scheduled at this particular time, two-thirds of the way through the study to share with you, Mr. Chairman and the committee, the data that we know to date. The best information we have as of this hearing today, it is the result of two phases of a 3-phase study being completed.

The first phase was conducted at Colorado State University. That is not anecdotal data. They do not do anecdotal research. They are a first class research operation. This data was garnered from one plant, the first of I believe eight plants that we are going to be doing the commercial tests in to cover, not just steers and heifers, but other types of animals.

Ms. FOREMAN. Did you say that in your testimony, Pat? Did you say it, Gary? Nobody pointed that out in the testimony.

Mr. BOYLE. But the Department is well aware of the stages. In fact, Ms. Foreman, we would be happy to walk you through the first two phases and also what we embarked upon in Phase III. In fact, Mr. Chairman, it took us a while to get to Phase III, the actual commercial tests, because we had to work extensively with the Department so that all parties agreed on the protocol to be sure that the data that was generated from the study would actually provide the kind of information the regulators felt they needed to make an informed decision on trim versus wash.

I am very glad to hear Acting Assistant Secretary Jensen commit to this committee prompt action. I have to tell you in all honesty, the record that goes back well before Ms. Jensen's journey from Minnesota to the Nation's Capitol does not suggest that even with extensive data, the Department is capable of prompt action. I will give you one brief anecdote that is very similar to what we are talking about here. It has to do with carcass prewashes.

We began pilot testing prewashes in a plant in 1985. As Mr. Wilson indicated, that pilot test lasted 6 years. It demonstrated overwhelmingly huge reductions in all sorts of pathogens on the carcasses, just by misting the carcass. Six years we tested it, generating data year after year after year. We were asked to conduct a scientific literature review. We commissioned Texas A&M to do so. We submitted that in May of 1990 to the Department. The fifth year the pilot test, with a formal petition, asked that they approve this technology. We then had the study conduct a \$400,000 industry-funded study in 1992 to have further documentation that misting a carcass will dramatically reduce *salmonella* and *E. coli* and *listeria*.

In November of 1992, in the seventh year, USDA authorizes the use of carcass prewashes, finally. In March of 1993, as part of the zero tolerance initiative and the memo that you just read from Dr. Horn, Mr. Chairman, you will notice that it explicitly states that the trimming of the carcasses must occur before the washing, which in effect precludes us from beginning to use in commercial application the carcass prewashes that we spent 6 years trying to get approved. So that technology, although it is well known that it works, is now sitting idle in plants because we have to trim the carcasses before they can be misted.

Senator KERREY. What is the reason for that and why was that conclusion reached?

Dr. REED. Let me add to that, Senator Kerrey. The rationale was if there was fecal material on there before inspectors had a chance to observe it or before the company trimmed it, then it would be washed and spread throughout the entire carcass. That is being looked at again. In fact—

Senator KERREY. In the face of the studies that show that there is a reduction—are you not making that judgment based upon an anecdotal conclusion yourself or are you making that judgment based upon evaluation of some evidence?

Dr. REED. I cannot explain why the decision in March was to discontinue that process. I have observed that process as recently as 2 weeks ago in your home State. I have asked several of the manufacturers there to resubmit the data to make sure that there is not gross contamination with fecal material prior to the washing of those carcasses. If we can accomplish that, then I think we can wash those carcasses before evisceration.

Because what we are talking about is removal of accidental contamination with foreign matter. We are not talking about gross fecal contamination, and gross fecal contamination as a result of poor manufacturing practices, not good manufacturing practices. Or, after the carcass is opened up, there is a mistake made and something is cut. I think those are two different circumstances, but the accidental contamination with foreign matter from the hide, I think does get washed off very effectively from those preevisceration carcass washes and agreed to take a second look at that and get those reinstated.

Senator KERREY. So what does that mean, agreed to take a second look at it? You moved very quickly in March of 1993, but the policy really was sort of half-anecdotal—I mean it was quick and decisive and I appreciate that—but what I am saying is if I am sitting out there and now responding to your request to resubmit the data, I am sitting there, and there was no resubmission of data in March of 1993. What is the timetable on it? How do you adjust a policy—again, keep in mind that I do not want to backtrack off the goal and indeed would like to open this thing up so that we can change the culture in the field to actually improve the health environment for consumers. How do you change now? How do you propose to change a policy and be able to continue to advance toward improving the quality of product?

Dr. REED. We changed because the basic goal and the basic fears are the same, the basic goal is to remove the contaminants.

Senator KERREY. I mean how, under what circumstances do you change? What conclusions do you reach? What is the basis by which you are going to allow, or disallow the wash to occur?

Dr. REED. On the preevisceration carcass washes a variety of industries have been hesitant to ask for this because they did not know whether they would be successfully approved. So the asking for that process and the controls associated with it have not been there in every plant. They have been in a very, very few. What Mr. Boyle and others have suggested, as we took away those things in March of 1993 by letter, and we did that in a very quick spirit in an effort to do something to remedy a situation.

Senator KERREY. Say that again. We did that in a very quick, spirited effort?

Dr. REED. Effort to remedy a situation.

Senator KERREY. Quick spirited effort to remedy a situation. What situation did you remedy?

Dr. REED. We are looking at preventing pathogens on food.

Senator KERREY. No, you are looking at ingesta, fecal material and milk on food.

Dr. REED. OK, but there is some association. I do not think anyone would disagree with that.

Ms. JENSEN. Mr. Chairman, let me add—

Senator KERREY. I do not disagree there is some association, it is just that I do not know what the association is. That is the problem. I mean, you put in place a rigid policy, quickly put in place, in response to consumer concern that I share. "Now, the question is, how do you improve the policy? We have got it in place. How do you improve it? Or do you just sit there and say, show me, show me. How do you—"

Dr. REED. No, that is not it at all. I think what we do want to do is be willing to deal with washing the carcass, getting the accidental contamination off, preevisceration, and I think we are moving forward rapidly on that. There were two considerations on that. One was a visible defect detection, and one was a moisture consideration. Early in my tenure in FSIS, there was a consideration that carcasses would literally pick up water and producers would sell water when it was not declared.

Senator KERREY. Let us assume that I am operating a plant out there, Sir, and let us say I have 1,000 people working for me, and I generate \$30, \$40 million for the year in sales or whatever. Then I come to you and I say, here is a procedure that I am willing to put in place. It is not the trim policy; it is an alternative. Let us say it is a combination of procedures that I think is going to be better. Let us say, you allow it. Who takes the risk? Who is at risk for changing the procedure? I am.

If I produce a product—assume you and I are going to do a deal here now. If I produce a product that is contaminated and a consumer gets sick off of the thing, who suffers the consequence? USDA or me? I am the one that is at risk. I have manufacturers out there saying I am willing to take that risk. I am willing to change my procedures. You tell me, what you want. I am willing to change the procedures. I will accept the risk and it is my business that is at stake.

Why not engage in that kind of a discussion? Why not engage in a specific plant-by-plant discussion with people that are prepared to accept higher quality standards than what we have in place right now and use good science and evaluation. Why not just begin. What do you need me to do? Why do we need a damn law to do it? I see the law sitting there right now allowing me to do it. Let us just do it. I do not understand all of this. I really do not. I do not understand this *manana* business. I mean I have got "manana infections" all around me anyway. Why not just get out there and try it. Hello.

Dr. REED. We, in fact, will be trying it.

Ms. JENSEN. Mr. Chairman, let me say on behalf of the Zero Tolerance Policy here that when the Secretary has moved quickly in these particular instances, it was always with the consumer in mind. We had had a tragic foodborne illness outbreak in Washington and if there is a doubt about a specific way of doing something, we want to air on the side of protecting the consumer and making the foods safe. That is, after all, what we are charged with. What we are trying to do now is to go into a system that is science-based and we wish that we could move science quicker. I mean, we wish in cancer and so many areas that we could move science to give us answers and all that we want.

But we do feel like we are getting more science and we are getting more evidence and we are working on tests such as the one—

Senator KERREY. Honestly, I think it is too top down with all due respect. I think it is too top down. I think the changes that you listed, and I do not remember what they all were, but I do not know why we cannot put a procedure in place that is more site specific. If you have got a bad plant out there, shut them down. That is not an issue. If you have somebody out there that is putting out contaminated food, shut them down. I am not debating that at all.

What I am trying to do is say, we have a very important part of our industry, a very important part of our economy—and again I get a picture of 1,600 people out there that are working. They get pay checks. They have families. We all give great speeches about jobs, jobs, jobs, and they want to know why did you shut my plant down? I am sitting there saying, well, I really don't have a very good answer. Why not just immediately say to our reconfigured folks out there, you are no longer inspectors. You are health specialists. You issue an order that you are going to go out there and work with the plants. If you can come up with a scientifically-based procedure that improves what you are doing right now, allow the manufacturer to assume the risk and do it.

Ms. JENSEN. We are not necessarily in disagreement.

Senator KERREY. Then let us do it. Let us save Senator Daschle the trouble of holding another hearing.

Ms. FOREMAN. Can I make just three quick points. First of all, when the *E. coli* outbreak happened, the Department dragged up every old dog and cat that it had never gotten through and took it out and said, this is the pathogen reduction program, Track I.

Number two, you do have to have proof that somebody is contaminating the product before you shut them down. That is what you are trying to get the Department to come up with.

Number three, you could get them to do that if you would say to Acting Assistant Secretary Jensen and Secretary Espy, we would like to have a series of dates, days by which you will have the things you say that you will get. If we get there and find that science has not turned up the answer, you can always have an extension.

But ask for specific dates by which these things will be concluded. I have been waiting since January of 1993 for a trace-back system. We have all been waiting, everybody at this table. Ask for dates and then when the Department does not come up with something by that date, make them explain why they have not come up

with it by that date. Some days they will and sometimes they will not be able to.

Senator KERREY. My dilemma with that is that again it presumes that we are going to do it the same all over the country.

Ms. FOREMAN. I am talking about science.

Senator KERREY. I am talking about science as well, but I am also talking about an operation that is ongoing. It is not a scientific experiment out there in the field, as I see it. I share the objective. In fact, I would like to have tougher objectives than we have in place right now. I would like to improve the confidence that the American consumer has in the product.

In my opening statement I told you about 21 Nebraska youths who went out in a Boy Scout retreat and ate hamburger and got sick. The epidemiological studies on that indicate that they probably had the 0157:H7, whatever the number is, that caused them to get sick. So I say, the policy did not work. Why did it not work? My view is that it is rigidly applied top down. It is not based upon good science. There are lots of ways to improve it, so let us improve it. Let us just start doing it. If you need a law changed, tell me you need a law changed. There are lots of improvements in the system, it seems to me that could be made immediately to improve the confidence that the American consumer has in their product.

Mr. BOYLE. Mr. Chairman, two quick points. One, I was struck by one of the reasons that Dr. Reed cited for not approving the carcass prewash. Because of the concern that the 1,200 pound carcass would gain water weight through a misting process. We have studied that and maybe, I am not aware of it, but maybe there is an ounce or two or three or four, maybe there is even a pound of water that gets sucked into that 1,200 pound carcass. Even more importantly—there are tolerances up to 8 percent for water gain in poultry products—but more importantly, it reduced the pathogen level. The Department's reliance upon that water issue, the concern of economic adulteration, is indicative of the fundamental change that has to occur there.

We have a system that is worried about producers selling water to consumers and not concerned about technology that reduces the pathogens that go on raw products. That defies common sense to us and it has been indicative of the mind-set for a long time. Hopefully this hearing today will begin to turn that mind-set around.

One other comment. You asked early on, Mr. Chairman, what can they do now, given the current system that is out there? Maybe we need some legislative changes and regulatory reform, but what can they do now? In 1985, the National Academy of Sciences told them what they could do. Again in 1987, NAS told them what they could do. The Food and Drug Administration has followed that precedent with seafood inspection and led the way to show us what we can do.

Why cannot this Department—14, 15 months after the *E. coli* outbreak—promulgate a regulation to mandate HACCP programs for meat and poultry plants in this country? AMI has supported this for years. We formally wrote the Secretary earlier this year. We do not understand why after six field hearings around the country last spring, a 2-day facilitated conference on inspection reform here in the Washington area in November, yet another 2-day

HACCP round table here in Washington a month or so ago, and all the studies, all the recommendations, and again the continuing leadership with the Food and Drug Administration, why cannot this Department promulgate a HACCP regulation? That would be a tangible, positive regulatory step towards reform that has been long overdue.

Senator KERREY. What is the answer, Ms. Jensen?

Ms. JENSEN. The proposed regulation is just about ready to be published. We did have the round table and we had commissioned a facilitator to lead that round table. They then needed some time to issue a report. The report was sent out to the participants. We are not dragging our feet on the HACCP. I might tell you that—

Senator KERREY. Just about to be promulgated means when?

Ms. JENSEN. We are talking within several weeks and during the summertime this year. I mean we are not talking 6 months, 8 months; we are talking—

Senator KERREY. Several weeks—1 or 2, 2 or 3?

Ms. JENSEN. Let us say that by the end of the summer. Carol was asking for dates. Let us say by the time you—

Senator KERREY. End of the summer, by the way, is several months, not several weeks.

Ms. JENSEN. The first part of August or so, I would say. It is a matter of getting the report, getting the comments back from the round table. For us not to do this, would be to ignore the round table and to ignore that process of involvement. It is—

Senator KERREY. You will promulgate the rules and you will get comments, will you not? You will get comments after the rule is promulgated and people in the round table that did not like what you promulgated can object.

Ms. JENSEN. Exactly.

Senator KERREY. I would not worry about it. I mean, just get it out.

[Laughter.]

Senator KERREY. Really.

Ms. JENSEN. Mr. Chairman, it sounds so easy when you say it.

Senator KERREY. It is easy. Promulgate it. I mean, let us promulgate the rule and have a discussion of it.

Ms. JENSEN. We will.

Senator KERREY. A couple of weeks, too. Not August, people start cooking out soon. Somebody started talking about hamburgers earlier, and I started getting hungry; so let us do it in a couple of weeks.

Ms. JENSEN. Mr. Chairman, you will have your proposed rule as soon as we can get it out there and hopefully that will be within a couple of weeks.

Senator KERREY. Give me a date, come on. When can you have it done?

Ms. JENSEN. By August 1. Mr. Chairman, let me tell you that with the HACCP—

Senator KERREY. June 15—tell me why you cannot have it done by June 15?

Ms. JENSEN. Because one, the proposed rule goes to the FEDERAL REGISTER. For me to discuss with members of the round table their

experience is *ex parte*. I gave them a commitment that they would come around the table. We would get the report to them from the facilitators. They would get those comments back. We would put the rule in. It would be going back on that commitment. Once that rule is——

Senator KERREY. So you now have till Monday. Write the rules, circulate it, and get their comments.

Ms. JENSEN. That is the process we are——

Ms. FOREMAN. Part of the law here is once the rule is promulgated, once it is proposed——

Senator KERREY. How many round table members are here at the table? So let us get it done. Are you going to be offended if they do it by June 15?

Ms. FOREMAN. I asked for the round table in August last year. I never could figure out why it took till March 29 to have it. However, the fact is, that the rule has not gone to the Office of Management and Budget yet, so she cannot tell you it is going to be out by June 15, because they will take it for some time.

Senator KERREY. Then why has it not gone to OMB?

Ms. JENSEN. Because the facilitators sent the report a certain time after the round table, and that report was disseminated to members of the round table. Their last input——

Senator KERREY. What is missing, Ms. Jensen, is a sense of urgency that parallels the urgency that is felt by consumers and parallels a sense of urgency that is felt by people who are working out there. I just say with great respect for the process and I do not know who is going to be offended, but I worry about giving offense to consumers and giving offense to working Americans out there who depend upon getting this thing promulgated.

I am not trying to subvert the process—well, maybe I am trying to subvert the process, if it means it is going to take till the 1st of August. That is two-thirds of the way through the summer.

Ms. JENSEN. Mr. Chairman, industry can implement HACCP without this. We did this at Pillsbury Company years ago when I was there. This rule is not necessary for HACCP. There are many responsible industry people in this room who probably already have HACCP. So the rule itself is not going to halt HACCP programs. As I said, I am very proud that I worked for the Pillsbury company——

Senator KERREY. But it will affect the way you regulate industry.

Ms. JENSEN. It is just a mandatory——

Mr. MARSDEN. Can I comment on that?

Senator KERREY. Yes.

Mr. MARSDEN. I am Jim Marsden with the American Meat Institute. A good example of why we need the HACCP regulation. HACCP stands for hazard analysis and critical control points. In the beef slaughter process, the main critical control point that has been researched, identified and implemented is organic acid prewashed systems. We are not using those to any degree today because of the zero tolerance initiative.

But since the Department is relying on enforcement, on inspection, on organoleptic evaluation, rather than on science, prevention and process control, industry, at least in the slaughter area, is not capable of implementing hazard processes that are effective.

Senator KERREY. Ed?

Mr. ZADJURA. There has been a lot of conversation about the preevisceration carcass wash and zero tolerance. To some extent they are somewhat—

Senator KERREY. Would you, just for the record, establish your credibility here by describing your visitations to plants and so forth.

Mr. ZADJURA. Ed Zadjura from GAO. I am the Assistant Director for Food Safety and I have asking the same questions about—

Senator KERREY. But you have been out in the field?

Mr. ZADJURA. We have been all over the place.

Senator KERREY. I did not mean your title to establish credibility, I meant your—

Mr. HARMAN. Ed is very modest. He has spent, I do not know, 5 or 6 years of some intensive work throughout this food safety system.

Mr. OLESON. Keith Oleson, I am with GAO also, Senator. We have contacted 157 meat and poultry plants just on our last effort, not counting the ones we visited before then. We actually visited 76, where we actually went into plants and reviewed what their programs were, especially in regards to microbial testing. That is where the basis of our knowledge comes from.

Mr. ZADJURA. The preevisceration carcass wash and you heard the whole long story about how long industry tried to get it approved and everything, and all the research tends to indicate it is a great thing and ought to be used and does reduce contamination. It does not effectively or would not effectively make any changes to the Zero Tolerance Standard. Because one of the places they would be looking would be after evisceration and any fecal material, ingesta or milk that the inspector sees is on there, the Zero Tolerance Policy as it currently exists, would still require to be trimmed. There may be other methods and there is some ongoing research that shows that at that point, instead of trimming you could have an additional wash of some kind to wash that contamination off, as opposed to having to trim it off. That has not—Mr. Boyle has his ongoing studies and that—but that has not necessarily been absolutely documented as yet.

The other thing about this is saying that they do not have to—they can go ahead with HACCP, that is true. We have been out. We have visited plants. They are doing that. Yet again, as you talked about flexibility under the HACCP concept a plant, if it met the standards, it would have their option of how to do it. A plant might actually choose to, for some reason, trim. Or they might choose to wash, as long as they can demonstrate that they were meeting the standards, including microbial.

So you can have a voluntary HACCP, but does not work with today's system, because you would still have to trim if anybody can see it. So there are a lot of different discussions. HACCP would get you to the variable. It would be up to the plant to design a control system, as long as they can document, and show that it was working, and meeting the standards—if USDA ever promulgates HACCP—and approves any standards. That can be a long time, as you know.

Mr. BOYLE. Right now, Mr. Chairman, there are a number of plants that have HACCP programs in place. One, because it is the best process control technology we know about today and it makes good business sense to implement it voluntarily. Some are moving in that direction because we believe that at some point, the recommendations from the National Academy of Sciences will be implemented by USDA and it will be required. We think the regulation is important, because it will mandate that type of process control technology in all plants, all 8,000 plants, not just those that presently think it is the right thing to do or a good thing to do.

The chain is only as strong as its weakest link. We sell a lot of product that is unbranded. We think all the plants that are manufacturing raw meat and poultry and processed meats in this country should be doing so pursuant to HACCP. An AMI board of director's motion cannot accomplish that. A Federal regulation can and we would like to see it move in that direction.

Senator KERREY. Ms. Foreman.

Ms. FOREMAN. Since I helped you beat up on the Department, let me say that originally the Secretary told them to get the HACCP regulation out by last August. We went to the Department and said, we have been shut out of here for 12 years. Nobody talked to us. In the last few months, we have been talking to the Agency and we think that there are serious problems with the HACCP plan they are putting together. Could we have the opportunity to discuss with you, Mr. Secretary, and your new staff, some of our concerns with it. Part of the reason you have had this delay is that they did do that, and they have done it. Once again, took a little longer than anybody thought maybe it would take.

But you know that proposing the rule is no action. Proposing the rule is just the first step. Frankly, had they gone ahead with the rule last August, we would have gone to court. I am absolutely certain we would have prevailed. You would have delayed this thing a very long time. In the long run, that consultative process, not shutting out—

Senator KERREY. You are not threatening to sue me, are you Ms. Foreman?

Ms. FOREMAN. I threatened last year.

Senator KERREY. OK.

Ms. FOREMAN. Because nobody had talked to us. We had real problems. Now I think—

Senator KERREY. Is that what you do when nobody talks to you, you sue them?

Ms. FOREMAN. Damn right.

Senator KERREY. Lord help us.

Ms. FOREMAN. It is my government too.

Senator KERREY. I understand. I appreciate that.

Ms. FOREMAN. So we do appreciate the fact that—and we think that the rule will be better now when it comes out.

Senator KERREY. Mr. Wilson.

Mr. WILSON. Senator, I would like to go back to a basic question of the zero tolerance initiative and how can we resolve the current issue that we are in, and getting back to the research. It is true the research is ongoing. We hope to have it accomplished in the

near future. The Department has been very instrumental in helping outline protocol and being involved in every step of the way.

I guess our question, my question as a producer, because we do have money involved in this project, as we do for many other research initiatives on *E. coli* 0157:H7. If the Department has their project at Texas A&M and it is proposed that that project is not going to be accomplished until December, this one should be ready by July, is there an opportunity to the Department to review this and initiate some phase in? Or must we wait till the A&M study gets completed and then we will all sit down together and do this and we will resolve the zero tolerance issue some time next year or 1995? Is there an opportunity to take this project, review it, and initiate some implementation at the grassroots level or must we wait for a Boeing 747?

I think everyone around the table and this has gone on for years, everyone is waiting for the 747 to roll off the line. Why can we not build a nice Piper Club to get started here, when it is based on scientific principle and eventually we will move to 747 or Cadillac or Lexus, whatever you want to call it?

Senator KERREY. Basically what is going on, it seems to me, is we have tests being done by the industry and tests being done by USDA with no real sense that the two paths are ever going to converge.

Mr. WILSON. I think the basic goal or initiatives, objectives of the research is the same. I do not know that there has been cross collaboration between Texas A&M scientists and CSU scientists. Maybe there has been, but the Department has been involved—

Senator KERREY. How are the paths going to cross? Are they going to cross—

Mr. MARSDEN. They have crossed. Can I comment on that?

Senator KERREY. Yes.

Mr. MARSDEN. What we are doing, both government and industry, is a specific study to contrast washing and trimming to try to find out the best system to achieve the zero tolerance. There are years of data out there that suggests that washing is effective in both removing visible contaminants and also in reducing microbiological contamination. So the Department could move. The Department does not have to wait until December to get everything together. There is a lot of data out there currently that would support washing carcasses. They could evaluate that data and move within a week to do that.

Senator KERREY. We are going to close the hearing. I am going to tell you that my inclination is to hold one of these on the first Tuesday of every month. The issue is too important to me, just too darn important to let the policy drift and drift and drift. It is important for consumers and it is critically important, as well for American working people.

It just seems to me that, as I hear the testimony, there is common ground. There is common ground that the policy needs to change. There is an urgency to change the policy and base it much more on good science than we currently do. We are all concerned about back-tracking and saying to the American consumer that we do not care about your health and your safety. So I am going to say, I hope the rule is promulgated before August 1.

However, I will say to you as well, with great respect, my inclination is to hold, even in addition to the one that Senator Daschle was referencing as to the proposed administration's law, my inclination is to hold these things regularly until we begin to get even greater confidence that we are making progress. I thank you.

This hearing is closed.

[Whereupon, at 11:43 a.m., the subcommittee adjourned, subject to the call of the Chair.]

A P P E N D I X I I

PREPARED STATEMENTS

PATRICIA JENSEN

Mr. Chairman, and Members of the subcommittee, it is a pleasure to appear before you today to discuss the Department of Agriculture's activities to improve the meat and poultry inspection system. I am pleased to follow-up on the food safety issues that time did not permit me to address, when I appeared before the subcommittee on February 10, 1994, and to update you on the progress USDA has made to date.

Secretary Espy and I take our mission to protect the public health very seriously. Unfortunate as they are, the continuing sporadic outbreaks of foodborne illness caused by pathogens are forceful reminders of the urgency of our assignment. Just last month, 21 persons in Nebraska, including a group of Boy Scouts who consumed undercooked hamburger, were victims of an outbreak associated with the *E. coli* 0157:H7 bacterium. The Department and other Federal agencies, State agencies, the meat and poultry industry, the scientific community, consumer groups, and Congress must work together to safeguard the food supply.

Early last year, Secretary Espy laid out a strategic pathogen reduction plan that addressed steps in the farm-to-table continuum where the potential for food safety problems may be reduced. The Secretary's Strategic Plan is based on risk principles advocated by the National Academy of Sciences and the General Accounting Office in their recommendations for improving the safety of the Nation's food supply.

As I reported in February, we have over 70 initiatives underway in the agencies under Marketing and Inspection Services. I would like to submit for the record an updated set of charts that reports the progress made on each of these initiatives and I would like to discuss a few of them at this time.

Enforcement

To safeguard public health, Secretary Espy has directed the Food Safety and Inspection Service (FSIS) to emphasize stricter enforcement of sanitation and other food safety requirements in meat and poultry plants.

To control a potential source of pathogenic bacterial contamination, the meat and poultry industry must produce carcasses that are free of all fecal, ingesta, and milk contamination. At this time, trimming is the only approved means for removing such contaminants from beef carcasses. FSIS food inspectors examine all carcasses to see that industry meets requirements, including proper trimming. I will discuss later our efforts to seek scientific evidence that other methods may be viable alternatives.

Scientific studies have confirmed the presence of pathogenic bacteria, including *E. coli* 0157:H7 and *salmonella* in the feces of cattle. These microorganisms, as well as other enteric pathogens associated with fecal material, can be isolated in the hooves and hides of cattle. During the slaughter process it is not possible at the present time to completely eliminate contamination of carcass surfaces with pathogens—bacteria cannot be seen. However, contamination of carcasses with fecal material is visible and it should be removed to make carcasses as safe as possible.

The National Advisory Committee on Microbiological Criteria for Foods (NACMF) defined the critical limit for fecal materials as zero occurrence at the Critical Control Point established at evisceration. The NACMF model identifies the corrective action for fecal contamination as immediate trimming of the contaminated areas on the carcass.

USDA, through the Cooperative State Research Service, awarded a cooperative agreement on the basis of competition for the conduct of a study to determine the relative efficacy of trimming versus washing of carcasses to remove pathogenic bacteria during beef slaughter operations. The study is now being conducted at Texas A&M University, to evaluate trimming, water washing, and organic acid washing treatments. Results are due by December 1994. These results and other scientific information will be used to update our policy on the enforcement of zero tolerance. USDA welcomes scientific information from outside sources. To this end, FSIS worked with the National Livestock and Meat Board and the American Meat Institute to review and approve a protocol, for a study of the efficiency of beef trimming versus washing study being funded by these two industry organizations. FSIS will use the in-plant data from this study, which is being coordinated by Dr. James Reagan of the National Livestock and Meat Board, to assist in developing future policy on cleaning of carcasses.

Considerable care has been taken to ensure that the clean meat policy is being implemented, fairly and uniformly, at cattle slaughter plants. Constituent groups were solicited for input into the guideline development process. In January 1994, five Regional Correlation teams were trained to carry out in-plant training activities. By May 9, 1994, on-site training for all slaughter inspection personnel at the 870 Federally-inspected beef slaughter plants in the continental United States and Puerto Rico was completed. Plant management representatives were also invited to attend these correlation sessions. Oral instructions, written instruction packets, video tapes, and a question-and-answer period were elements of each session. Correlators spent time with Inspectors In Charge and Circuit Supervisors on the kill floor to cover additional supervisory instructions. Based on written feedback from inspectors, we believe the correlation effort was largely successful, and we are following-up on instances where inspectors indicated they needed additional guidance.

We recognize that with an inspection force of over 7,000, there may be concerns about uniformity and consistency of enforcement. Any inspector or plant operator can request a followup correlation training session. We are responding quickly when any of these problems are brought to our attention. For example, we recently sent the FSIS Deputy Administrator for Inspection Operations to Nebraska to review our activities there. We are continuing our correlation activities in Nebraska and have been in daily contact with inspection personnel and plant owners to ensure uniformity and consistency of enforcement.

Federal standards, including clean meat standards, must be enforced by States maintaining their own inspection programs. Last week, State Inspection Directors from States with meat inspection programs received correlation instructions. We will continue to work with the States and our Meat and Poultry Advisory Committee to ensure uniform enforcement.

Secretary Espy has announced that USDA will further enhance and strengthen the poultry inspection system to include microbial improvements and the prohibition of all fecal matter on raw product. This reinforces a zero tolerance standard for poultry. In 1993, scientists completed a study that reconfirmed previous studies establishing the efficacy of washing. As a result, we will continue to permit washing as a means of reprocessing poultry that is accidentally contaminated by fecal material. New regulatory proposals under consideration would place additional requirements on the industry to control fecal contamination during the poultry slaughter process. Reprocessing is not allowed to be a substitute for prevention or good manufacturing practices. These proposals would include new inspection and control sites in the slaughter process, the use of antibacterial agents, and the establishment of regulatory standards that reinforce the Department's policy of prohibiting visible fecal contamination on any bird.

The Secretary also directed FSIS to establish a new Review and Assessment Division, which has completed a special review of 26 turkey plants operating under the New Turkey Inspection System (NTIS). This was the first review that included in-depth interviews with in-plant inspectors.

Last Fall, the Review and Assessment office also began a series of 1,000 unannounced meat and poultry reviews throughout the United States. These reviews are targeting meat and poultry plants suspected of having compliance problems and a significant number of other plants, selected to provide a general profile of industry compliance. The number of meat and poultry plants we are reviewing is proportional to the number of meat and poultry plants we inspect. For example, approxi-

mately 7 percent of all the plants we inspect are solely poultry operations, and approximately 7 percent of the reviews will be in poultry plants. Mr. Chairman, I would like to submit for the record, a summary of the number and kinds of reviews we are, and will be conducting in this special review cycle.³⁸

As with all reviews we conduct, we are taking immediate action when problems are found, including stopping operations when necessary. Over 300 plants have already been reviewed and we plan to pick up the pace this Summer.

When Secretary Espy took office, 90 plants were operating under Progressive Enforcement Action (PEA), which is an intensified inspection program that can lead to withdrawal of inspection and closure of a plant if problems are not corrected. In December 1993, 275 Federally inspected plants were operating under PEA after having been identified by FSIS special reviews or daily inspection operations as having significant problems. We believe the number of plants under PEA will fluctuate. We expect in time it may actually go down as plants recognize USDA is committed to strict enforcement.

Through Secretary Espy's efforts over the last year, and as part of the President's fiscal year 1994 food safety investment initiative, 200 additional inspector positions have been filled at FSIS. Although inspectors cannot see microbiological contaminants, there will be additional eyes and hands to observe and monitor carcasses and sanitary conditions in Federally inspected establishments.

Public Health Emphasis

To improve coordination with public health officials, Secretary Espy directed FSIS to create a new liaison position with CDC. The liaison officer has been selected and began work on January 9, 1994. This new position ensures that USDA has the most up-to-date information from CDC epidemiologists and medical professionals, thereby enhancing the public health activities of FSIS. This veterinary epidemiologist ensures that USDA is more involved in the tracking of outbreaks of foodborne illnesses and recently spent 2 weeks in Washington State and Oregon investigating recent cases of *E. coli* 0157:H7.

In addition to the FSIS/CDC position, Animal and Plant Health Inspection Service (APHIS) also has a full-time veterinary epidemiologist to facilitate communication and coordination between APHIS and CDC. This epidemiologist—working closely with his CDC counterpart, FSIS officials, and State public health representatives—traveled throughout the western States investigating the source of *E. coli* 0157:H7 contaminated ground beef that caused the January 1993 outbreak. Together, they developed recommendations for further research that could help reduce foodborne pathogens at almost every stage of the food chain from farm to restaurant.

Secretary Espy directed FSIS to officially establish a Public Health Division. This Division has been established and will assume the responsibility of establishing public health programs and policies, and maintaining liaison with Federal, State, and local government officials involved in the detection and control of foodborne disease. In addition, the Public Health Division will coordinate FSIS's response to emergency situations affecting the acceptability of meat and poultry products, coordinate voluntary recalls of contaminated product, and operate a foodborne hazard control center. A search is being conducted to select an individual with significant public health experience to head the division.

HACCP

USDA is drafting a proposed rule that would require that the meat and poultry industry to incorporate the Hazard Analysis and Critical Control Points (HACCP) approach in food production systems. The HACCP approach involves identifying critical control points and establishing critical limits for each critical control point. Each critical control point must have one or more measures that must be monitored to assure process control. Some of these measures, or critical limits, are established from chemical, microbial, or physical guidelines. HACCP guidelines may either be currently covered by USDA regulation, or may be derived from other sources.

Once critical control points and critical limits are established and approved, then the system must be routinely monitored for compliance. One means of monitoring is a careful review of records by inspection personnel. Verification that the limits are being met is accomplished by actual testing.

Each plant would be responsible for operating its own HACCP plan in a manner that maintains proper process control. If deviations occur, the plant would be responsible for making adjustments to assure process control. If there were repeated plan deviations, or if plans were not properly followed, FSIS would take regulatory

³⁸ See Appendix II, pages 185 and 186.

action. Such actions could include: increased intensity of verification; increased product testing; increased external audits; suspension of a particular process; and use of either retention or condemnation authority.

USDA sponsored the HACCP Round Table in Washington in late March. This forum allowed representatives from USDA and all of our constituent groups to engage in open and frank discussions of all issues relative to implementing HACCP systems. The issues raised at the Round Table are being considered by FSIS as it develops a proposed rule for mandatory HACCP in meat and poultry plants.

Risk Assessment

The degree of risk food presents to the public health is attributable to the inherent nature of the food itself, the environment in which it is grown and processed, and the effectiveness of the controls used in its handling, storage, and cooking. As a result of these variables, Secretary Espy determined that USDA's food safety initiatives must include each step of the production of food—from farm to table.

Secretary Espy is committed to moving meat and poultry inspection from just organoleptic examination to one that is more risk-based and grounded in the latest science. A major objective of USDA's current research program is to determine the exact nature of risk associated with bacterial contamination of meat and poultry during slaughter and processing.

Risk-based inspection is the concept of implementing a broad spectrum of policies and procedures based on the risk presented by a product, a process, or a facility. Formal risk assessment requires four analytical steps: hazard identification, hazard characterization, exposure characterization, and risk characterization. The results of risk assessment can present a range of policy alternatives for consideration. Risk management is the process of weighing those policy alternatives and selecting and implementing appropriate regulatory options.

Risk communication is the final step in the process and involves an interactive exchange between regulators and stakeholders concerning identified risks and regulatory options.

While chemical risk assessment has received a good deal of research focus, few attempts have been made to assess the risk posed by microbiological agents. The reasons for this are many, but include the fact that the concentration of microbiological agents is not static—that is, their numbers increase or decrease—and furthermore, that humans vary greatly in their susceptibility to the varied biological agents that may be present in food. Thus, illness from foodborne biological agents is more difficult to predict, in terms of exposure, than possible exposure to chemical hazards.

The National Advisory Committee on Microbiological Criteria for Foods established a Working Group on Risk Assessment in 1993 with a charge to provide advice on the further utilization of risk assessment strategies as a means of identifying levels of risk associated with bacterial pathogens in meat and poultry products. Issues discussed by the Working Group include, but are not limited to, issues of minimal infectious dose, prioritization of risk by organism, interpretation of available data, and identification of data gaps.

As its first task, the Working Group is nearing the completion of a document entitled "Principles of Risk Assessment for Illness Caused by Foodborne Biological Agents." This document will recommend definitions, requirements, procedures, and alternative approaches for risk assessment; identify data gaps; provide methods for developing reasonable estimates to fill data gaps; and present a prototype model for risk assessment. The Working Group has not yet determined an example to demonstrate the application of principles, although discussions have focused on either *Campylobacter jejuni* or *Salmonella*. We expect the committee to formally adopt its recommended Principles report in the fall of 1994.

FSIS has begun the process of incorporating quantitative risk assessment into the qualitative risk assessment and empirical experience that currently underlies the inspection system. Policy options that are based on risk data will increasingly become routine features of regulatory options undertaken by FSIS. It is expected that early risk assessment efforts will be improved by later scientific information and will themselves require re-examination over time. Basic research to understand microbiological health concerns and their control in slaughter and processing plants, for example, can take 3 to 5 years. Such scientific research must subsequently be used to develop policy options, operational implementation guidance, and instructions for the inspection workforce. It is anticipated that most risk analyses will be lengthy, but the time period from the start of an individual risk assessment project to its implementation in the field will be shortened as we gain experience using risk data.

FSIS has also begun the process of orienting employees to risk analysis concepts and has encouraged dialogue through two risk assessment seminars held in 1993.

Preharvest Activities

Our focus is not only on the slaughter and processing plants; it also includes the entire food chain from farm to table. For this reason, the Pathogen Reduction Program includes a preharvest food safety focus. Preharvest food safety deals with the beginning of the food chain—on the farm where meat and poultry production begins—and continues through transportation to the slaughterhouse. Preharvest food safety activities are primarily the responsibility of the Department's Animal and Plant Health Inspection Service (APHIS).

APHIS is uniquely qualified for preharvest food safety programs because of its work in animal health, its traceback capability, and a longstanding relationship with State animal health and public health officials. We already have in each State an infrastructure ideally suited to conducting emergency traceback investigations, and we periodically conduct mock animal disease emergencies to keep our field work force and investigation techniques well honed in the event of a real emergency. APHIS also runs the National Veterinary Services Laboratories, which are staffed and equipped to diagnose virtually any livestock or poultry disease and serve as reference labs for other diagnostic facilities across the country.

In addition, APHIS maintains a staff of animal health experts, statisticians and epidemiologists whose primary function is to monitor animal disease outbreaks, develop animal disease control models, and perform traceback investigations when called upon to do so. For example, even before the *E. coli* tragedy occurred in the Western United States, this staff conducted a national survey of *E. coli* O157:H7 in dairy heifers, which is used today as the basis for national prevalence estimates of *E. coli* O157:H7. From this study, we learned that there is no geographic pattern for *E. coli* O157:H7, and that it appeared in less than one percent of those animals tested. Prevalence studies were also conducted for *Salmonella* and *Cryptosporidia*.

In March, APHIS held the first meeting dedicated to exploring the myriad of program options that fall under preharvest food safety. APHIS invited representatives from industry, trade associations, universities, consumer advocacy groups, State Government, the Centers for Disease Control, the Food and Drug Administration, and several USDA agencies. The 2-day meeting was attended by over 100 people and resulted in excellent participation in subject overviews and roundtable discussions.

One important outcome of this meeting was the formation of a project team assigned to develop the strategic and operational action plans for APHIS' preharvest food safety efforts for the next 2 to 3 years. By evaluating what we have done up to this point, working closely with industry on quality assurance initiatives, and cooperating with universities to develop research priorities, the team will develop eight specific goals, objectives and activities for the coming years. APHIS hopes to implement many of these strategies quickly at the beginning of fiscal year 95, which is the first year for which we have requested line-item appropriations for preharvest food safety activities.

One of our future goals, and the core of APHIS' involvement in preharvest food safety, is the development of pathogen reduction models for use on the farm. APHIS' work on another foodborne illness, *Salmonella enteritidis* (SE), serves as a potential model for other preharvest programs. Under the SE traceback program, poultry flocks implicated in human outbreaks of SE are placed under restriction until the status of the flock is determined. While under restriction, eggs can only go to plants for processing; they cannot be marketed as table eggs. If the flock is determined to be infected, restrictions remain in place until the flock is negative to tests. Models for other health issues that affect meat and poultry will take some time to be developed, but are critical to minimizing the existence of foodborne pathogens on the farm, and preventing their spread to other points along the food chain. An integral part of developing these pathogen reduction models will be identifying critical control points and developing intervention strategies to address the problems most likely to occur.

Another essential component in our effort to keep pathogens in meat and poultry to a minimum is examining the food safety programs used in Europe. Because the United States maintains much larger production units and more diversified marketing channels, it is fair to say that agricultural production, food preparation and food safety norms in Europe cannot be compared side-by-side with those in the United States. Nevertheless, we feel it would be valuable to learn from these countries' experiences, both good and bad. In some instances, countries such as Denmark, Germany and Sweden seem to have made tremendous strides in limiting the occurrence of *Salmonella enteritidis* other *Salmonella* species, and *Campylobacter*. As the

European experts continue to develop new ways of dealing with emerging food safety issues, we look forward to working closely with them to see if their successes would apply to our production system.

APHIS' preharvest food safety operational goals for the current fiscal year include working with the U.S. meat and poultry industries to improve existing identification and traceback systems and promote quality assurance programs.

Microbiological Testing

An important component of Secretary Espy's Strategic Plan is nationwide, microbial baseline studies to determine the presence and levels of pathogens on meat and poultry. These profiles will give USDA critical yardsticks against which to measure progress to reduce risks associated with microbial contaminants. The data may also be useful in enabling scientists to isolate particular problem areas by species, location, seasonal conditions, and other factors.

In October 1993, FSIS completed its first year of data collection for the microbiological baseline survey of steers and heifers and a final report has been issued. Samples from plants whose combined production totaled 99 percent of all fed cattle slaughtered in the United States were included in the survey's sample population. Over 2,000 cattle were sampled, and nine individual microbiological tests were conducted on each sample. No pathogens of any kind were found in 85 percent of the samples. *E. coli* 0157:H7 was found in 0.2 percent, or four of 2,081 sample carcasses.

A similar survey is underway for bulls and cows, a major source of ground beef. A microbial baseline study for poultry began in February 1994, and will be followed by a swine survey. In August 1993, a ground beef survey and a disabled cow survey were initiated. Samples of ground beef from 600 establishments were collected through February of this year. The results will enable us to assess the prevalence and levels of microorganisms in ground beef at the time of manufacture. The University of Georgia Veterinary Diagnostic Laboratory is assisting USDA in analyzing samples collected from disabled cows for the presences of *Salmonella* species, *E. coli* 0157:H7, and *Campylobacter jejuni/coli*. We are examining whether animals under stress present a higher risk of being a source of microbial pathogens.

Rapid detection of microbial contamination on meat and poultry products is a major goal of USDA. In a FEDERAL REGISTER notice of October 21, 1993, FSIS described the circumstances under which it would evaluate test kits and specified the performance criteria which it considered necessary for in-plant rapid methods. In a *Commerce Business Daily* (CBD) solicitation of November 19, 1993, the Agency identified the technologies which it considered most promising in terms of their potential and requested that companies working with these technologies advise the Agency if they believed their work could be applicable.

Also, in a series of Requests for Proposals (RFP), appearing in the CBD beginning March 24, 1994, FSIS is seeking competitive offers for work in these areas. Fundamentally, FSIS is seeking development of technologies, particularly rapid read-out technologies, that can be used by Agency inspectors in a plant to measure bacterial counts on equipment, instruments, surfaces, and product. However, because biohazards still exist in the enrichment process needed to produce detectable levels of organisms, in-laboratory technology is also being considered. Analytical methods the Agency is examining include:

- *bioluminescence*—for testing the hygiene of facilities and equipment, and for determining the biological load carried on products;
- *immunofluorescence*—for environmental testing of rinses, diptanks, brine and flavoring vats, and surfaces;
- *biosensors*—for detecting low levels of specific organisms;
- *immunoassays, such as ELISA tests, and nucleic acid probes*—to determine the presence of pathogens or toxins in enrichment cultures of products and environmental samples;
- *nucleic acid amplification methods, such as PCR, LCR, and Q-Beta replicase*—for more specific pathogen testing with little or no enrichment needed;
- *microbial typing systems, such as ribotyping, isoenzyme typing, and restriction endonuclease analysis*—for specific confirmations of bacterial organisms and to better trace the source of these organisms;
- *automated microbial identification systems*—to improve the accuracy of microbial identification and/or increase analytical capability; and
- *equipment for measuring pH, water, and temperature levels and to determine end-point times and temperatures.*

Using bioluminescence technology as an example of USDA research in this area, USDA's Agricultural Research Service (ARS) is developing a rapid test at its Clay Center, Nebraska and its Athens, Georgia laboratories. It is hoped that the Adenosine Triphosphate (ATP) bioluminescence test will be able to detect within 5 minutes relatively high levels of general bacteria on carcasses. It is thought to be as accurate and repeatable as the 48-hour plate culture test currently used in laboratories to determine bacterial levels.

This test shows promise for supplementing FSIS' visual detection of fecal contamination on carcasses. The ATP test would provide an approximation of generic bacterial numbers, but not specific pathogens. This test might also be used to ensure equipment has been properly sanitized.

USDA also encourages companies to submit information on innovative, on-line process monitoring technologies, like machine vision or imaging technology, that can improve the Agency's process monitoring activities and become a fundamental component of the inspection system of the future.

FSIS has been tracking the development of imaging technologies, which are sometimes referred to as machine vision. Machine vision includes computer directed portion control equipment used in further processing. This equipment visualizes and controls high-pressure water knives to precisely cut products, such as pork bellies and chicken breast portions.

Researchers are adapting machine vision technology to identify visual nonconformances on carcasses during slaughter processing. This adaptation has become more feasible within the last few years as color monitoring capabilities have been successfully incorporated. The computer capacity limitations necessary for color imaging have for the most part been overcome.

As the research agency of USDA responding to the needs of FSIS, ARS is developing Spectral Radiometry, a machine vision method, as an on-line inspection tool for poultry inspection. The objective of the project is to develop a real-time, efficient system capable of detecting abnormal poultry carcasses, based on their spectral characteristics in ultraviolet, visible, and near-infrared light. They are also planning to study the feasibility of rapid detection of *salmonella* with optical techniques.

Additional work is being done by researchers at Georgia Tech to identify condemnable poultry carcasses based on their differing absorption of various wavelengths of light. Their efforts include detection of visible fecal contamination and aesthetic nonconformances such as bruises and broken bones. Imaging using infrared light or other combinations of light wavelengths has the potential to allow machine vision technology to detect nonconformances that may not be seen in visible light.

FSIS is also embarking on a major initiative to integrate microbiological testing throughout the inspection system. This is being done in three ways.

For preoperational sanitation, FSIS will employ random micro-monitoring to supplement daily visual inspections of plant sanitation programs. This environmental sampling program will provide valuable information about the relationship between the visual appearance of facilities and equipment surfaces and the level of microbiological contamination. It will also provide inspectors with valuable experience in microbiological principles and sampling techniques that will be helpful as we incorporate more microbiological testing into the inspection program. A broad-scale pilot test of the program will begin this spring. National implementation in meat and poultry slaughter and processing plants will be phased in beginning in October.

During the slaughter process, FSIS will begin microbiological monitoring of carcasses before they enter the cooler. These results can be used to track the plant's process control system to minimize bacterial contamination. Samples will be collected and analyzed for indicator organisms, such as APC, coliforms, etc. A pre-trial that includes this microbial critical control point monitoring is now underway in five beef plants. Similar trials will be conducted in poultry plants. A broad-scale pilot is scheduled to be carried out this summer, and nationwide implementation in beef slaughter plants will begin in October 1994.

FSIS is extending its current microbiological testing program for processed, ready-to-eat products to additional types of products not currently covered. Especially important is the fact that FSIS initiated microbiological testing of cooked, ready-to-eat meat patties produced in Federal establishments. This supports our regulation that mandates cooking temperatures for pre-cooked patties. Microbiological sampling for uncooked cured meat products was conducted in October 1993 and for cooked patties in December, 1993. Sampling is expected to begin in May 1994 for dried, cured, or fermented products. Ready-to-eat products found to contain any pathogens are considered adulterated.

Regulatory and Legislative Initiatives

We have recently received the results of an independent study comparing regulations for meat and poultry inspection. Differences detailed in the study have resulted primarily from statutory language of the Federal Meat Inspection Act (FMIA) and the Poultry Products Inspection Act (PPIA), or from historical practices of the meat and poultry industries.

Some examples of these differences include mechanically deboned product, the amount of water added to product, and reprocessing procedures. As you may be aware, to attempt to equalize the mechanically deboned meat and poultry issues, we have already issued a proposed rule on mechanically deboned meat and an advanced notice of proposed rulemaking on mechanically deboned poultry. We are evaluating other methods used to chill poultry and will determine whether current regulations need to be reviewed.

Legislative changes may be necessary to provide the Secretary the statutory authority to ensure there will be no gaps in our ability to address food safety issues from the farm to the table.

Interagency Coordination

In keeping with another promise Secretary Espy made last year, the Pathogen Reduction Task Force has been formed. This task force, which the Secretary has asked me to chair, is responsible for leadership, coordination and oversight in USDA's efforts to reduce pathogens in meat and poultry.

As this task force moves forward, we will be examining the results of the many projects USDA already has underway. The results of these projects may be the key to where we head in the future. We anticipate adding more initiatives as we move forward and as new technology becomes available. We believe it is critical to maintain both close interagency cooperation and a systems approach to integrate and focus the many resources in the Department, including research and education components in our efforts to reduce pathogens. The Task Force includes members of other Federal agencies, such as CDC and FDA, to ensure that all our efforts are well-planned, coordinated, and implemented effectively.

We are working with State and local health and regulatory officials concerned with preventing foodborne disease. Last week USDA and FDA experts conducted a video teleconference to update these officials on recent HACCP initiatives, discuss key new provisions of the Food Code with emphasis on the importance of proper cooking temperatures, and review the role of education in preventing foodborne illnesses.

Consumer Education

Another part of the Pathogen Reduction Program is consumer education. No matter what we are able to accomplish in live animals or in packing houses, consumers will continue to play a role in ensuring the food they prepare and cook is safe. A final rule mandating safe cooking and handling labels for all raw and partially cooked meat and poultry products was published in the Federal Register on March 28. I have with me today a chart showing what consumers will be seeing on these labels.

As of May 27, all raw and partially cooked ground meat and poultry products, such as hamburger and sausage, must bear a safe handling and cooking label. All other not-ready-to-eat meat and poultry products must have the label by July 6, which coincides with the date that USDA will require nutrition labeling on processed meat and poultry products. We applaud the many members of the food industry who are already labeling their products with safe cooking and handling instructions.

Earlier this month, I was in Atlanta to launch a food safety education campaign targeting children and parents coast to coast with the announcement of the distribution of more than 2 million postcards bearing an important message about only eating cooked hamburgers that are brown in the middle. Undercooking could allow pathogens that might be present to survive, so thorough cooking is not only common sense—it's another way parents can protect their children's health.

In Atlanta, I hosted a picnic for children from the F.L. Stanton Elementary school to teach them firsthand about looking at the middle of the hamburger before they take a bite. In terms of educating consumers about safe food handling, "look before you bite" is an important precaution we learned from the *E. coli* outbreak in the Western States. The simple step of cooking a hamburger until it's brown in the middle will help ensure that there are no pathogens present to make consumers ill.

I am pleased to report that the National Association of School Nurses, who helped kick off this campaign with me in Atlanta, will help distribute the postcards through 21,000 school nurses across the Nation. In addition, other USDA agencies,

including the Food and Nutrition Service and the Extension Service will help distribute the postcards.

Parents Bob and Laurie Galler in New York and Darin and Vicki Detwiler in Seattle, held news events at schools in their respective cities announcing the distribution of the postcards, which will include 1.7 million in English and another 250,000 in Spanish. As you may know, the Gallers lost their 3-year-old daughter, Lois Joy, to Hemolytic Uremic Syndrome (HUS) in 1992. The Detwilers in 1993 lost their 2-year-old son, Riley, after he contracted HUS when he came into contact with another child infected with *E. coli* 0157:H7. The Gallers, the Detwilers, and many other families have been strong advocates for better education to consumers and an improved meat and poultry inspection system.

As spring and summer approach, and people begin cooking hamburgers out on their grills, it is vital to get out the safe food handling and cooking message. This campaign will help us further spread the word about safe cooking and handling of meat and poultry products. We specifically wanted to spread the word about hamburgers to children and their parents because hamburgers are popular with children.

As you can see, the postcard features a full-color photo of a hamburger with the caption "Recipe for a Safe and Delicious Hamburger. No matter how you top it . . . Before you take a bite, make sure it's brown in the middle." The card also lists several safe cooking and handling instructions.

Each postcard costs less than 2 cents to print but each one placed in a parent's hand becomes priceless. It can help save that child's life.

Thorough cooking of meat and poultry products has been an important part of USDA's messages on food safety targeted to consumers and commercial food handlers. USDA has worked closely with FDA to establish time and temperature requirements for various meat products, including cooked hamburger patties and has completed rulemaking that requires fully cooked hamburgers prepared in Federally-inspected establishments to be cooked following a range of time and temperature combinations sufficient to destroy all pathogens. Similarly, USDA's poultry regulations require that all heat-processed poultry products be cooked to an internal temperature of 160 degrees Fahrenheit. Cooking to these temperatures has proven to kill pathogenic bacteria in meat and poultry products. USDA's Meat and Poultry Hotline is conducting a survey of callers to determine who uses cooking thermometers and why. This research will enable us to better target consumer education messages regarding the importance of thoroughly cooking meat and poultry products.

We have also enhanced our consumer education efforts through the FSIS Food Safety Education Branch. This unit is designing public health information projects that present the public with simple yet compelling messages on food safety. These projects include: a grant to the National Agricultural Library to set up the USDA/Food and Drug Administration (FDA) Foodborne Illness Education Information Center; the hamburger education campaign I mentioned earlier; and the preparation of extensive press and consumer information publications explaining what the new safe handling labels for meat and poultry will mean for public health.

Distribution of a new USDA/FDA food safety package began this month. The safe food directives package, with an emphasis on how to protect against *E. coli* 0157:H7, will be sent to 9,000 fast food restaurants as well as to national organizations serving the restaurant community.

In addition, USDA's Meat and Poultry Hotline received more than 130,000 calls during 1993. These calls usually involve questions about how to safely handle, cook, and store meat and poultry products.

Summary of Plans for 1995

In fiscal year 1994, Congress approved the Administration's request for an additional \$8 million for pathogen reduction activities. In fiscal year 1995, the Administration, as part of the President's Investment Initiatives for USDA, is requesting an additional \$25.8 million. The additional funds for pathogen reduction will be targeted at improving the system from the farm to the table. FSIS would receive an additional \$5.8 million; APHIS, \$5.7 million; the Economic Research Service, \$0.2 million; and \$14.1 million for research and extension.

With funds requested in the fiscal year 1995 budget, we will expand our multi-agency efforts for pathogen reduction. At the preharvest end of the system, we will propose a traceback system for determining the sources of microbiological contamination at the farm level. Efforts will also be undertaken to develop educational programs for food producers and handlers to encourage adoption of production practices that limit contamination by pathogens and other hazards. For the slaughter and processing segment of the system, inspectors will be trained in the latest food safety

techniques, rapid testing methods will be developed, and new production practices that may reduce or eliminate contamination will be evaluated. We are also requesting \$7.7 million to hire and train an additional 200 inspectors to ensure that we have all the necessary personnel in place to ensure compliance with food safety standards.

These efforts will be supported by and coordinated with the Department's research agencies. Consistent with the farm-to-table approach to reducing pathogens, USDA researchers will devote resources to develop improved production methods and will strive for advances in processing technology, including new meat and poultry inspection tests to identify bacteria levels rapidly and improved slaughter methods. Newly developed technologies will be demonstrated to producers and handlers of meat and poultry products through increased food safety education.

Conclusion

In summary, Secretary Espy has pledged that we will have a science-based inspection system, a focus on public health, tougher enforcement, improved consumer education—including safe handling labels. That's the direction we're going now and the direction we will maintain for the future. It's an approach that goes from farm to table, and one USDA is uniquely qualified to handle.

Thank you again, Mr. Chairman, for inviting me here today. I'm happy to answer any questions you or other Members of the subcommittee have.

Comparison of Plants Receiving Unannounced Reviews With All Federally Inspected Plants

(Number/Percentage by Type of Inspection)

Type of Inspection	All Federally Inspected Plants (4/13/94)	326 Unannounced Reviews (as of 4/20/94) 1/	Projected Completion of 1,000 Plant Review 1/
Plants Approved For Poultry Inspection Only	456/7.0%	19/5.8% 2/	67/6.7%
Plants Approved For Meat Inspection Only	2,184/33.3%	95/29.1%	314/31.2%
Plants Approved For Both Meat and Poultry Inspection	3,916/59.7%	212/65.0%	625/62.1%
TOTAL	6,556/100%	326/100%	1,006/100%

1/ This Column does not include the 34 reviews conducted at 26 plants with the New Turkey Inspection System (NTIS).

2/ Includes 12 plants with chicken slaughter operations, 2 plants with turkey slaughter operations and 5 plants that have poultry processing inspection only.

1000 Plant -- Unannounced Reviews

Status as of October 27, 1994

Type of Inspection	All Federally Inspected Plants (9/21/94)	Plants Reviewed (10/1/93 - 10/27/94)	Projected Completion of 1,000 Plant Review
Plants Approved For Poultry Inspection Only	451/7%	43/6%	6%
Plants Approved For Meat Inspection Only	2121/33%	222/30%	33%
Plants Approved For Both Meat and Poultry Inspection	3931/60%	481/64%	61%
Total	6503/100%	746/100%	100%

JOHN W. HARMAN

Mr. Chairman, and Members of the subcommittee: We are pleased to be here today to discuss recent efforts to improve the ability of the Federal meat inspection system to prevent food poisonings similar to those in January 1993 that caused several deaths and hundreds of illnesses. You asked that we comment on the progress made by the U.S. Department of Agriculture (USDA) and its Food Safety and Inspection Service (FSIS) to detect harmful bacteria in meat during slaughter and processing operations. More specifically, you asked that our testimony address (1) what changes have been implemented in the meat inspection system, (2) how effective these changes have been, and (3) what still needs to be done to provide consumers with a safe meat supply.

In summary, while FSIS has made some changes, the inspection system is only marginally better today at protecting the public from harmful bacteria than it was a year ago, or even 87 years ago when it was first put in place. FSIS' recent efforts have neither dealt with the inspection system's inherent weaknesses nor fundamentally changed the system's predominant reliance on sensory (sight, smell, and feel) inspection methods. These methods cannot identify microbial contamination, such as harmful bacteria, which is the most serious health risk from meat and poultry. Although FSIS has known about this problem for 15 years or more, its major initiative in response—creating a new inspection system—is still years away.

In fiscal years 1993 and 1994, USDA budgeted about \$45 million and about 440 staff years, to put together a program of 81 projects to improve its current inspection system, such as (1) proposing a regulation mandating the use of package labels describing how to handle and cook meat and poultry safely, (2) undertaking over two dozen data collection and research projects, and (3) implementing stronger oversight of meat and poultry plants with a high-risk profile. In addition, FSIS has begun a long-term effort to study how the inspection system can be completely revamped to better protect public health.

FSIS' recent efforts have probably lowered the chance that people will become ill from eating meat contaminated with harmful bacteria. For example, because of FSIS' efforts to provide information, consumers and retail food establishments are now more aware that raw meat products must be properly handled and cooked to control or kill bacteria. Also, FSIS' more vigorous enforcement of the current sanitation and slaughter processing regulations will indirectly help control bacterial contamination by eliminating some potential sources of contamination. However, the ability of the inspection system to detect harmful bacteria, evaluate how serious the problem is, and take corrective action remains limited. FSIS has not established a regulatory program requiring plants and inspectors to routinely test for harmful bacteria. Such testing is the only conclusive means to determine whether (1) sanitation and processing controls are working properly and (2) the product is free of contamination.

As GAO and others have repeatedly stated over the past 15 years, a new, scientific, risk-based inspection system is needed to better protect the public from foodborne illnesses. Such a system would allow FSIS to target its resources towards higher-risk meat and poultry products by increasing inspection of such products, developing methods or tools that would help inspectors detect microbial contamination, and/or increasing the testing of such products.

Before we provide more details on our findings, we will give you some background on the current inspection system.

Background

At the turn of the century, Upton Sinclair's *The Jungle* raised a public outcry about contagious animal diseases, unsanitary conditions, deceptive practices, and lax Government inspection at meat packing plants. The Congress responded to this outcry by passing the Federal Meat Inspection Act in 1907. This act and a subsequent poultry act require Federal inspection of meat and poultry to ensure that they are safe, wholesome, and correctly labeled and packaged. To achieve these objectives, the acts require that each individual animal carcass be examined at the time of slaughter by an on-line USDA inspector.³⁹ In this traditional inspection, largely unchanged for 87 years, inspectors make judgments about disease conditions, abnormalities, and contamination in animals and carcasses on the basis of what they see, feel, and smell—a process known as organoleptic inspection.

After slaughter, meat and poultry from Government-inspected carcasses can be inspected again during further processing. (Processing operations can include simple

³⁹ In fiscal year 1992, FSIS inspectors visually checked 89.2 million swine, 30.8 million cattle, 5.1 million sheep and lambs, 1.8 million other livestock, and 6.8 billion poultry.

cutting and grinding, complex canning procedures, or the preparation of ready-to-eat products.) FSIS implements the Federal inspection laws by requiring that all meat and poultry processing plants be visited daily by a USDA inspector, who may spend from 15 minutes to several hours performing various inspection duties. These inspections, also, rely primarily on organoleptic methods.

Nevertheless, the safety of meat and poultry remains a concern. While inspectors may indirectly identify some microbial contamination using these traditional methods, they cannot see, smell, or feel the presence of microbial pathogens. FSIS and others have recognized that such pathogens now present the greatest risk to public health from eating meat and poultry. Because many cases of foodborne illness go undiagnosed, the actual number of incidents may well be much higher than the Centers for Disease Control's estimate of 6.5 million annually and, according to FDA, may reach 80 million or more. The Centers for Disease Control has recognized that meat and poultry products are a primary cause of foodborne disease. USDA estimates that the annual cost of foodborne illness in the United States ranges from \$5.2 billion to \$6.1 billion, with more than half of this amount—\$3.9 billion to \$4.3 billion—attributable to meat and poultry.

FSIS HAS TAKEN INITIATIVES TO BETTER PROTECT THE PUBLIC FROM HARMFUL BACTERIA

In response to the tragic *E. coli* poisonings in January 1993, FSIS announced a 2-track plan to update the meat and poultry inspection system. Track I, currently under way, is a near-term plan for maximizing the effectiveness of the existing system. Track II, initiated in 1993, is described as a longer-term effort aimed at overhauling the entire system. FSIS estimates that the modernized system developed in Track II will be in place by the year 2000.

On January 27, 1994, FSIS provided us with information on 81 individual projects undertaken as part of Track I. These projects, which are at various stages of development, generally fall into four categories:

—*Strengthened oversight and regulatory enforcement.* Stronger oversight of meat and poultry plants was the focus of 28 projects. For example, projects included assigning more experienced inspectors to plants that slaughter higher-risk animals; developing a profile of "problem" plants and making unannounced, special reviews of plants fitting the profile; and writing new rules to strengthen record-keeping requirements. As with FSIS' routine inspections of slaughter and processing plants, these new initiatives rely on organoleptic inspection procedures.

—*Greater consumer awareness.* Efforts to increase consumer awareness of the potential hazards of raw meat and poultry were involved in 15 projects. The most significant initiative in this category is the well-publicized proposed regulation that would mandate that all raw meat and poultry products sold at retail stores include a label on safe handling and cooking procedures. While consumer education should help reduce the number of outbreaks of food poisoning¹ it will not eliminate them. For example, since the *E. coli* outbreak of January 1993, the Nation has experienced an increase in the number of incidents of foodborne illnesses caused by meat contaminated with the same *E. coli* bacteria.

—*Data collection, research, and studies.* Various initiatives to collect data, conduct research, and perform studies of microbial pathogens comprised 32 projects. These projects include national baseline studies of bacteria found on carcasses at slaughter plants, research projects to determine the cause and source of harmful bacteria, and the publishing of criteria that biotechnology firms should consider when developing quick tests for detecting microbial contamination. These initiatives could potentially help prevent foodborne illness in the long term, but in the near term do not preclude such incidents.

—*Stricter procedures for slaughter and dressing.* Stricter slaughter and dressing procedures to reduce the potential for bacteria from intestinal sources to contaminate the carcass were the subject of six projects. These projects involve requiring that carcass and boneless meat surfaces be free of visible contamination—the so called zero tolerance standard. These stricter procedures should help reduce the incidence of foodborne illnesses by indirectly reducing some potential sources of microbial contamination. While there is believed to be a high correlation between the presence of visual contamination and microbial contamination, the correlation is not absolute. Further, there are other sources of microbial contamination that can

not be identified visually. Therefore, the zero tolerance standard does not ensure that inspectors will be able to identify microbial contamination.

FSIS INITIATIVES DO NOT HELP INSPECTORS IDENTIFY AND EVALUATE BACTERIA

While FSIS has made some constructive changes and undertaken numerous research and data collection projects, it has not yet overcome the inspection system's inherent weaknesses nor made the fundamental changes needed to better protect the public from the most serious health risk from meat and poultry—microbial contamination.

With advances in animal and veterinary science, many infectious diseases have been controlled, thereby decreasing the human health hazard posed by animal diseases. In contrast, microbial hazards associated with the crowding of animals and other factors have grown. FSIS clearly recognized this change in risk in its 1991 report to the Congress. In that report, FSIS concluded that microbial hazards present the greatest risks posed by meat and poultry to public health.

None of the 81 FSIS initiatives undertaken under Track I have changed the labor-intensive, organoleptic process used at meat and poultry plants. During visits to meat and poultry plants, we watched inspectors using knives, flashlights, mirrors, and thermometers. While inspectors may identify some contamination using these traditional methods and tools, they cannot see, feel, or smell microbial pathogens. Experts have increasingly questioned the public health benefits of FSIS' reliance on organoleptic inspection. According to a 1985 National Academy of Sciences report, while organoleptic inspection serves its original purpose of protecting consumers from grossly visible lesions or diseases, it cannot identify microbial pathogens—today's principal health risk. Similarly, an October 1993 conference of the World Congress on Meat and Poultry Inspection—an international association of Government regulators from meat trading countries—concluded that postmortem organoleptic inspection must be changed because (1) it wastes resources and cannot detect microbial pathogens, (2) the animal diseases for which it was originally designed have been eradicated in many countries, and (3) it results in unnecessary cross-contamination because the hands-on inspection techniques used virtually ensure that contamination is spread from one carcass to another.

Based on past work, we would like to highlight two limitations that are especially relevant to the current inspection system. First, current laws restrict FSIS' flexibility to respond to changes in the level of risk. Regardless of the risk to public health, FSIS is required by law to perform continuous inspection at slaughter plants—examining every carcass—and to visit each processing plant daily. Because of these requirements, the Agency is limited in its ability to adjust inspection frequencies and target its resources to respond to changing risk.

Second, although FSIS has known for many years that microbial contamination was a serious problem, it has not routinely performed microbial tests of equipment surfaces or raw products, nor does it require industry to perform such tests. As a result, FSIS does not know where in the production and processing cycle microbial contamination is most likely to occur, or what types of bacteria are prevalent and at what levels. Such information is needed to design and implement an effective control program. FSIS now recognizes the need for such information and has initiated various research and data collection efforts.

Recognizing the importance of microbial testing, some plants have set up microbial testing programs on their own to ensure the safety and quality of their products. For example, one plant we visited started a microbial testing program to check on the effectiveness of its cleaning procedures. Test results indicated that even though cleaned surfaces had passed FSIS' inspection, some of these surfaces still contained high levels of bacteria. Company management therefore revised its cleaning procedures to reduce bacteria levels.

While self-initiated plant programs have resulted in worthwhile changes, they also vary in their effectiveness because sampling methodologies, types of tests performed, and test evaluation criteria differ from plant to plant. FSIS has not developed industrywide guidelines or standards that define a safe level of bacteria to help those plants that do perform microbial tests, nor has FSIS attempted to collect or disseminate the results of these testing programs to help other plants correct similar problems.

Scientific, Risk-based Inspection System is Needed

Although experts agree that the intensity and type of inspection should be determined by the risk a particular food presents, the current meat and poultry inspection system is not based on risk and is not able to adequately protect the public

from harmful bacteria. Labor-intensive inspection procedures and inflexible inspection frequencies drain resources that could be put to better use in a risk-based system.

In March 1993, shortly after the *E. coli* poisoning incident, we testified that to protect the public from unsafe meat and poultry, FSIS needs to move to a scientific, risk-based inspection system.⁴⁰ Such a system would allow FSIS to better target its resources towards the higher-risk meat and poultry products by increasing the inspection of these products developing methods or tools that would help inspectors to detect microbial contamination, and/or increasing the microbial testing of these products.

One concept for improving the scientific basis for regulating food safety is a production control process known as Hazard Analysis and Critical Control Point (HACCP). This process consists of identifying the likely hazards that could be presented by a specific product and then identifying the critical control points in a specific production process where a failure would likely result in a hazard being created or allowed to persist. These critical control points are then systematically monitored, and records are kept of that monitoring. Corrective actions are also documented.

On May 27, 1993, the Secretary of Agriculture directed FSIS to publish in 90 days a plan for carrying out his decision to mandate that all meat and poultry plants set up HACCP systems. However, even though USDA has been actively pursuing HACCP for 3 years, FSIS has not yet proposed any regulations, decided on specific requirements for plant HACCP systems, or decided on whether it will require microbial testing to monitor or verify a system's performance.

Conclusions

The present inspection system cannot effectively identify and prevent meat contaminated with pathogenic bacteria like *E. coli* from entering the Nation's food supply. It still relies primarily on organoleptic inspection procedures that are not capable of detecting such pathogens—the greatest public health risk associated with meat and poultry. FSIS' initiatives to improve the inspection system have not addressed this inherent weakness, nor has FSIS sought requirements for routine microbial testing by industry or Government inspectors.

To better protect the public from foodborne illnesses, FSIS must move to a modern, scientific, risk-based inspection system. Such a system would allow FSIS to target its resources towards the higher-risk meat and poultry products by increasing inspection of these products, developing methods or tools that would help inspectors detect microbial contamination, and/or increasing the microbial testing of these products.

This completes our prepared statement. We will be glad to discuss meat and poultry inspection issues further with you, other subcommittee Members, or your staffs.

J. PATRICK BOYLE

More than a year has passed since the U.S. Department of Agriculture vowed to revolutionize this Nation's antiquated meat and poultry inspection system. During that time more than 500 million tax dollars have been spent by the Food Safety and Inspection Service (FSIS), more than 200 new inspectors have been hired and USDA has issued dozens of statements heralding inspection reform.

I am sorry to report that to date, the inspection system has changed little in any way that offers greater consumer protection. To my industry—which is dedicated to modernizing the inspection system—this is truly disappointing.

CURRENT ENFORCEMENT OF ZERO TOLERANCE POLICY DOES NOT IMPROVE BEEF SAFETY

Let me state clearly for the record: the meat industry supports the goal of USDA's zero tolerance policy, which is intended to control microbial contamination of beef by controlling potential sources of microbial contamination. Unfortunately, the strategy USDA has mandated for controlling contamination—hand-trimming visible contaminants off carcasses with knives—has in most cases increased, not controlled contamination. We now have data that show that inspection practices over the past year have not improved food safety by lowering microbial contamination of beef. The additional handling, cross contamination with knives and delayed carcass chilling associated with USDA's zero tolerance policy for beef have either had no effect or have actually increased bacteria on beef carcasses.

⁴⁰ *Food Safety: Building a Scientific Risk-Based Meat and Poultry Inspection System*, (GAO-T/RCED-93-22, March 16, 1993).

A survey of 15 major beef packing plants over the past year under the current zero tolerance enforcement shows that 11 (73 percent) reported an increase in total coliform bacteria counts on beef carcasses. Another study of 13 beef plants operating under zero tolerance during the same period shows that 10 (77 percent) reported increases in *E. coli* counts on beef carcasses. Two plants showed a decrease in counts and one plant showed no change.

Not only has the current zero tolerance strategy generally not reduced microbial contamination consumers, it has cost the beef industry an estimated quarter of a billion dollars in the past year alone.

This strategy, in effect, is failing to deliver consumers safer beef and asking them to pay more for it. Just for perspective, a quarter of a billion dollars exceeds the annual profit margin of the entire beef industry. Those costs—which result from trim loss, increased labor, plant down time and product shrink—are being passed forward to consumers and backward to cattle producers.

As a representative of the Nation's beef packers, I am asking for your support in convincing USDA that the current strategy used to enforce the zero tolerance policy is harmful to both consumers and the industry, and we must find a better way to achieve the same clean meat objective.

CARCASS WASHING DECREASES BACTERIA AND VISIBLE CONTAMINATION

In fact, there is a better way to remove both visible and invisible contaminants from beef carcasses than the zero tolerance method of hand trimming with a knife. It is carcass spray washing, using hot water alone or hot water in combination with an anti-bacterial solution. Researchers at Colorado State University (CSU) have demonstrated that the washing process is actually more effective than knife-trimming for cleaning up beef carcasses.

Two phases of a three-part study comparing beef carcass spray washing versus hand trimming have been completed. The first phase was funded by a beef packing company; the second phase was funded by the Colorado Beef Council through the National Live Stock and Meat Board. The third phase of the study begins this month and is funded by several beef packers and managed by both the AMI Foundation and the Meat Board. The protocol for this study has been approved by FSIS. In addition, four more universities will participate in this phase of the study.

Let me share some preliminary results of the study's first two phases:

Beef samples that were deliberately contaminated with bacteria and manure had an average of about 6.26 logs of bacteria per square centimeter. Identical samples that were hand-trimmed of visible contamination—in effect, the zero tolerance method—had a two log reduction in bacteria. But samples that were simply washed with a spray of hot water or treated with ozonated water or a dilute solution of hydrogen peroxide had a three log reduction in bacteria counts, representing a tenfold decrease in the number of bacteria relative to the trimmed product and a thousand-fold decrease relative to the inoculated sample.

Not only were bacteria counts lowest for washed beef as opposed to trimmed beef, but the researchers found the least visible contamination on washed samples as well. Researchers said their study suggests that “washing/spraying alone can effectively remove physical contaminants and can lower the microbial load on beef . . . without increasing the microbial load on adjacent surfaces.” Researchers also noted that, “In actuality, zero tolerance is a physical contaminant removal program and not necessarily a microbial-load reduction effector.”

CSU is joining with four other universities and four major beef packers to test these preliminary results in a variety of plant settings. If researchers from Kansas State University, Iowa State University, Texas A&M and the University of Wisconsin concur with CSU's findings, then we would urge USDA to move immediately to approve proper carcass washing procedures as an alternative to the hand trimming now required under zero tolerance.

Results from the in-plant phase of this research will be available within 60 days. AMI would be pleased to brief the members of this subcommittee as those results become available.

Meat and Poultry Inspectors Inconsistent and Retaliatory

The industry wants to work with inspectors and their supervisors in a cooperative, helpful and positive way. But the open hostility and retaliatory actions of a small minority of inspectors has undermined the entire inspection system and it must be stopped. The prevailing attitude among some inspectors seems to be that slowing or stopping peoples' businesses is their primary objective—irrespective of food safety concerns.

Zero tolerance is just one symptom of an inspection system in need of an overhaul. Problems associated with this policy have resulted in inconsistent enforcement on the part of inspectors and, in some cases, blatant inspector retaliation against plants. Neither FSIS nor USDA management has acted to correct these abuses of the system.

For example, one of the Nation's largest and most progressive beef packing companies recently invited a Senator to tour one of its Midwestern plants. The tour generated some media coverage in which the Senator questioned the enforcement of the current zero tolerance policy. Since those news accounts appeared, the plant has documented a 5-fold increase in inspector-generated down time, with no apparent reason except retaliation for the Senator's visit and public comments.

That plant has watched 1,600 workers stand idle while a single inspector repeatedly slows or stops the line in the name of zero tolerance. Nearly 100 jobs have been lost through attrition at this plant because of the economic hardship of abusive inspector enforcement.

Or take another example, a smaller, family-owned plant in the northeast that is among the finest in the industry—but is on the verge of being harassed out of business by inspector retaliation masquerading as zero tolerance. What was this company's offense? Complaining to USDA headquarters about inconsistent enforcement by inspectors. In this case, 750 employees stand to lose their jobs if the inspection abuse does not stop.

Inspector Workforce Needs Better Training

We agree with the inspectors' union and others that better inspector training will lead to better and more consistent inspector performance. We believe better employee training in our plants also leads to better performance, which is why AMI's goal is to train at least one HACCP expert in each of the Nation's 7,000 meat and poultry plants before the year 2,000.

There are currently some 8,600 meat and poultry inspectors working in the field. About 74 percent of those inspectors (6,400) have a grade status of GS-7, 8 or 9. They earn somewhere between \$23,400 and \$37,200 per year. About 72 percent of FSIS inspectors work in slaughter plants; about 26 percent work in processing plants.

What does it take to become a meat and poultry inspector? A high school education and either a few years working with meat or poultry in any capacity or, as a substitute, some related education such as a course in biology or animal science.

An entry level inspector is typically a GS-7 and is assigned to slaughter inspection. These are the individuals—72 percent of the inspection workforce—who are inconsistently enforcing zero tolerance and other policies and costing the industry huge sums of money, not to mention its reputation.

My members assure me most of these inspectors are well meaning, but it is inexcusable that an entry level employee with maybe no more than a high school education can idle 1,600 workers for days at a time and cost a company millions of dollars because that inspector has come up with a new interpretation of zero tolerance enforcement.

So I ask you, Mr. Chairman, to encourage USDA to increase both the technical training and the accountability they assign to these inspectors in order to help replenish the credibility this inspection system has lost.

Conclusion

In summary, AMI is asking for your support to accomplish three things:

1. Encourage USDA to adopt a better strategy for enforcing the zero tolerance policy: allow companies to use carcass spray washes as an alternative to hand-trimming to achieve a safer, cleaner product.

2. Urge USDA to take swift and serious action against inspectors who engage in retaliatory activities against plants. It would be useful for USDA to establish a system by which it can evaluate the appropriateness of inspector actions in plants relative to public health protection.

3. Hold USDA accountable for developing the scientific evidence to prove that any new policies, enforcement strategies or initiatives do not unintentionally worsen the safety of the food supply. Conversely, urge USDA to approve new technologies proven to enhance the safety of the food supply in meat and poultry plants.

Preventing foodborne illness is a serious matter. The meat and poultry industry is seriously committed to prevention and is investing millions of dollars in technology, training and research toward that end. USDA should show an equally serious commitment by adjusting its enforcement actions to improve food safety.

CAROL TUCKER FOREMAN⁴¹

Mr. Chairman, I am Carol Tucker Foreman. I appear today on behalf of the following members of the Safe Food Coalition: American Public Health Association, Consumer Federation of America, Food Allied Service Trades (AFL-CIO), Government Accountability Project, National Consumers League, Public Citizen, Public Voice for Food and Health Policy, Safe Tables—Our Priority, and United Food and Commercial Workers International Union.⁴²

Our Coalition is not a tightly organized trade association. We take positions only when an overwhelming majority of the organizations in the Safe Food Coalition agree with the stated position. Each time we testify, every organization reads and edits the text. When we have a document we can agree on, it becomes the Safe Food Coalition's position. I am usually the person who speaks for the group, but it is the members who decide what I will say. I mention this, Mr. Chairman, because the very short notice for this hearing has made it impossible to follow our usual procedure.

Foodborne illness is a serious health problem in this country. Representatives of the U.S. Government and the food industry brag that we have the safest food supply in the world. The Department of Agriculture spends \$600 million of our tax dollars each year to inspect meat and poultry, and every package of meat and poultry is stamped with the imprimatur of the Government. The stamp says, Inspected for Wholesomeness' or "Inspected and Approved, USDA."

Government and industry promise more than they deliver. Each year foodborne disease kills 9,000 Americans and makes between 6.5 and 80 million of us sick according to estimates by the Centers for Disease Control and Prevention (CDC). USDA's Economic Research Service says foodborne illness costs the American people between \$5.2 billion and \$6.1 billion each year. About one-half of the cost is attributed to meat and poultry products. When you add the cost of inspection to the cost of foodborne illness, the Nation is paying a very high toll for a program that is not very successful in meeting its goals.

Our meat and poultry inspection system is archaic and frequently ineffectual. As we approach the millennium, the inspection system is stuck at half past the century.

After the *E. coli* 0157:H7 outbreak on the west coast in early 1993, Secretary of Agriculture Espy promised to improve the system. One of his first steps seemed a simple and logical one. He pledged that USDA would begin to enforce the existing regulation of the Department which established a zero tolerance for fecal contamination of beef. "Zero tolerance" simply means that beef contaminated with feces, ingesta or milk cannot be processed. The contaminated meat has to be cut away. Feces, ingesta and milk are common carriers of the pathogenic bacteria that make people ill. I suppose it is not totally impossible to find sterile feces, but I wouldn't want to bet my health on it.

Whereas we can be pretty certain that visible fecal contamination reflects the presence of pathogenic bacteria, the absence of visible feces on meat does not guarantee that there are no harmful bacteria present. Zero tolerance for fecal contamination is a very crude tool, but it is the best tool USDA has available and is willing to use. The Department and the meat and poultry industry have avoided developing fast, effective tests to detect harmful bacteria and setting limits on the amount of disease causing bacteria that can be present on raw meat and poultry. That must change.

At least until a better system is developed, subjected to peer review, tested in a wide variety of plant environments, and found to be effective in keeping pathogenic bacteria below a critical level; the Safe Food Coalition supports the continuation of the zero tolerance for fecal contamination policy.

The National Cattlemen's Association (NCA) and the American Meat Institute (AMI), trade associations representing cattle producers and processors, argue that the application of the zero tolerance policy does not reduce or increases bacteria levels. As of today, those assertions seem to be supported only by anecdotal evidence. USDA should investigate their allegations, even invest in studies to determine whether they are accurate. But the Department should not change its existing policy without more proof than is presently available.

⁴¹Carol Tucker Foreman is president of the Washington, DC. public policy consulting firm, Foreman & Heidepriem, Inc. From 1977-81, she served as Assistant Secretary of Agriculture for Food and Consumer Services. Her responsibilities included direction of the Nation's meat and poultry inspection programs.

⁴²The Safe Food Coalition, an alliance of consumer advocacy, senior citizen, whistleblower protection and labor organizations was formed in 1987 to work for improvements in the Nation's food inspection programs.

Industry trade associations argue that high pressure washing is preferable to hand trimming for reducing bacteria. Again, the available data do not, in our view, warrant a change in policy at this time.

The industry also argues that the zero tolerance policy is being applied unevenly. We have heard similar charges that the policy is being applied vigorously in some plants and not at all in others. We urge USDA to investigate and act on these charges.

We also urge the Department to specifically clarify its definition of fecal contamination. We are eager to see that clarification in writing.

Neither NCA nor AMI are disinterested parties in this matter. Members of both lose money when fecal material is trimmed away. Producers and processors should not be penalized unnecessarily or inequitably. However, the cost of industry compliance is much less than the cost to consumers of foodborne illness. The cost of trimming is surely less than the high cost of a further loss of public confidence in the efficacy of the inspection system and of the wholesomeness of meat at the beginning of the cook-out season. Surely no one wants to send the message that industry or USDA endorses fecal contamination of beef.

The goal of meat and poultry inspection is to reduce the cause and incidence of foodborne illness. There is a far better way to achieve this goal. Industry and USDA should strive to reduce the presence of pathogenic bacteria on meat and poultry below a level that is likely to make humans ill. We believe the best way to achieve this goal is to:

1. institute a Hazard Analysis and Critical Control Point (HACCP) system;
2. require that plants using HACCP sample for pathogenic bacteria both at critical control points and at the end of the production line to verify that the HACCP program is working as intended; and
3. establish maximum acceptable levels of pathogenic bacteria for raw meat and poultry products. The HACCP program in each plant must be capable of regularly producing product that falls below these maximum levels.

These steps will not eliminate all pathogens, but together with USDA's public education program, they will almost surely help reduce foodborne illness.

GARY WILSON

Good morning! My name is Gary Wilson. I am Director of the National Cattle-men's Association's Animal Health Inspection and Research Committees. NCA would like to thank the Subcommittee on Agriculture Research Conservation, Forestry, and General Legislation for the invitation to participate in today's hearing.

The committee is to be commended for holding these hearings to address improvements to the Nation's meat and poultry inspection system. Let me make it very clear that NCA believes it is imperative for consumers and the beef industry, that the meat and poultry inspection system be effective and beyond reproach. Public safety concerning our products is of paramount importance. In the production process, cattlemen can invest up to 5 years getting an animal to market. Beyond that point we have no control on what is done with/to our product. Any negative concerns relating to inspection inadequacies impact consumer buying habits which in turn negatively impacts our market values.

NCA supports the establishment of a meat and poultry inspection system that is based on risk assessment, scientific analysis, and implemented in conjunction with Hazard Analysis and Critical Control Points (HACCP).

Visits with congressional leaders and staff have told us that the current Meat and Poultry Inspection Acts are written broadly enough to allow USDA to upgrade, improve, and modernize the inspection system. Subsequent visits with USDA reveal an opinion that the law does not allow for certain improvements/changes in inspection procedures or adoption of technology, and sights need for change in the law. Packing and processing companies can provide documentation indicating improved technology has not been implemented due to restrictions in the existing law.

In fact a good example is USDA's reissuance of the zero tolerance rule and the subsequent "hand trimming" requirement for removal of physical contaminants. Touted, by USDA, as a crack down on industry to help combat physical and microbiological contamination, has only filled the consumer with false hope. When first initiated last year, industry met with the Department to discuss the opportunity for instilling wash spray technology that had been successfully developed and implemented as a component of the Stream Line Inspection Pilot Test, and a technology already approved for slaughtering poultry. We were told that we needed to

conduct additional research. We asked for research supporting the current "trim-only" requirement. We were not surprised to learn that no research exists to support the current rule.

A recently completed research project known as the wash/trim study has concluded that a high-pressure (300 p.s.i.) hot water washing of beef carcasses followed by a bactericidal rinse, are effective at removing physical contaminants and far superior in reducing pathogen contamination on carcasses, than the hand trimming currently required. While we all agree and recognize that physical contaminants should be removed, let's also recognize the fact that additional handling of the carcasses by inspectors and plant employees actually contributes to microbiological contamination. I want to emphasize that the zero tolerance initiative is a fallacy. For a year it has cost cattlemen over 5 dollars per head for every animal slaughtered with no improvement in food safety. This is a classic example of the Department trying to use 1906 antiquated regulations and methods in dealing with today's problems.

Phase III of the project commercial application is currently underway. The final report should be ready for USDA review in July 1994. Our concern is that this research review will be held up by Government bureaucracy, inspectors union diatribe on efficacy and activist innuendo to install approval and use of this equipment as has occurred in recent years with other technology and initiatives.

For example incorporating HACCP principals into the inspection system was discussed by USDA's Meat Inspection Advisory Council 4 years ago, but the bureaucratic system in place today, along with political interruptions that influenced FSIS operation and vacancy in the administrator's office, indicates that the system we have is not capable of productive change within itself. There will need to be a complete paradigm shift in attitude and understanding from the Secretary of Agriculture's office to the inspector in the plant. It took 6 months to organize and conduct the now "infamous" HACCP Roundtable, and now we are told it will be another 6 months before release of the proposed rule. Who knows how long it will take to reach a Final Rule and implementation of HACCP.

Producers are tired of having the integrity of our products questioned while bureaucrats and activists quibble over round tables and job security. We must design an inspection system that takes advantage of the objective analysis and technological tools available today. We must have the courage to move beyond a system that inspects individual product, and incorporate one that inspects the processes under which the product is produced.

Producers and the packing/processing industry already spend over \$1 billion annually for product safety and quality control. This investment can complement a HACCP based system. New Government regulations should capitalize on voluntary industry initiatives. As we move forward on inspection reform, we should also take advantage of the opportunity to modernize and harmonize existing meat and poultry legislation and regulations. Consumers and industry can no longer afford to allow antiquated laws or regulations that hold back a modern science-based inspection system.

Regulations under the Federal Meat Inspection Act of 1906 and the Poultry Products Inspection Act of 1957 have evolved separately over the last few decades leading to numerous inspection, processing, labeling, marketing, and economic inequities between red meat and poultry products. Recently, the Research Triangle Institute of North Carolina, completed a report titled *Comparison of USDA Meat and Poultry Regulations*, and submitted it to USDA for its review. Hopefully, the Department will share the original report with the subcommittee as well. NCA is hopeful that this independent third party analysis will be helpful in identifying the laws, rules, and regulations that need updating, to a more modern, equitable inspection system.

The Secretary's public relation effort, that touts the budgeted addition of 400 inspectors in 1994 and 1995, is giving the consumer false expectations. This activity is setting the industry and the FSIS up for criticism when the next *E. coli* 0157:H7 outbreak occurs. Preventing microbiological contamination and the current inspection process is a contradiction in terms. The establishment of HACCP systems and utilizing improved technologies will best combat microbiological pathogens. I do not dispute the need for 400 additional inspectors if this is necessary to bring the current inspection system up to original standards for detecting animal disease and policing physical contaminants. USDA's information needs to be accurate in describing what the additional inspectors bring to the system.

Since 1988, NCA has asked the USDA to improve the meat inspection system by implementing new methodologies and technology that will help both plant employees and inspectors to do a better job of assuring safe and wholesome meat products. In 1990, NCA asked that epidemiological research and risk assessments be used to

develop strategies for control measures that would minimize the risk of human exposure to *E. coli* 0157:H7.

Our track record shows that cattlemen take the issue of food safety seriously. The NCA Beef Safety Assurance Task Force, formed in 1986, was novel in its approach in establishing a national producer education program. Today the beef industry has established an industry-wide Beef Quality Assurance Program designed to work with producers from cow-calf stocker and feeder operations in identifying management techniques that enhance the safety and quality of beef products.

NCA adopted policy in 1988 calling for more research on *E. coli* 0157:H7 and other pathogens that produce toxins in livestock and poultry. We have many questions that deal with this organism at the production level, and we are supporting research projects with check-off dollars to expand our knowledge base. In the past 4 years alone farmers and ranchers have invested over \$1.5 million to research *E. coli* 0157:H7, to develop tests for detection of this pathogen and to develop ways to manage this pathogen. Producers have earmarked \$1.2 million for further research in this area in 1994.

Some specific projects include:

Effect of Sodium Lactate on Microbial Safety and Consumer Acceptability of Precooked Roast Beef, Texas A&M University

Safety Enhancement of Partially Cooked Refrigerated Meat Products, University of Wyoming

Fate and Control of *E. coli* in Beef, University of Wisconsin

Detection and Control of Enterohemorrhagic *E. coli* 0157:H7 in Cattle, University of Georgia

Use of Natural Secondary Barriers to Inhibit Pathogens in Refrigerated, Cooked Roast Beef, University of Georgia

Determine the Efficacy of Organic Acid Rinses in Reducing the Level of Microbiological Pathogens on Beef Carcasses, (USDA approved this process in 1993)

Investigate the Effect of Cooking Practices (both conventional and microwave) on the Elimination of *E. coli* 0157:H7 and Foodborne Pathogens in Meat Cuts and Ground Beef

In an effort to help find needed answers, the beef industry formed a "Blue Ribbon" panel on *E. coli* 0157:H7 in September, 1993. Representatives serving on the panel include producers, industry scientists, food microbiologists, regulatory officials and public health professionals. They have been working to gather the most recent scientific data and testimony regarding this organism. The objectives include strategies on detection, control and intervention of this pathogen. A report will be finalized and published this June.

Let me conclude by saying that NCA supports efforts to improve the meat and poultry inspection system through the proposed Track I and Track II initiatives, even though 97 percent of foodborne illness is related to contamination beyond packing house and processing control as reported by the National Centers for disease Control. A farm-to-table approach will require the cooperation of all participants. Command and control systems which are punitive toward the industry will not be as effective as cooperative efforts directed toward mutually agreed upon food safety goals, even if those goals are extremely ambitious and challenging.

I am gratified and honored to be asked to participate in this important hearing. Thank you.

LETTERS

DEPARTMENT OF AGRICULTURE, OFFICE OF THE SECRETARY,
WASHINGTON, DC., May 24, 1994.

The Honorable AL GORE,
President of the Senate, Washington, DC. 20510.

Dear MR. PRESIDENT: Transmitted herewith, for the consideration of the Congress, is a draft bill "To amend the Packers and Stockyards Act, 1921, to provide authority to collect license fees to cover the cost of the program."

The Department of Agriculture recommends that the draft bill be enacted.

This proposal would amend the Packers and Stockyards Act (P&S Act) to provide authority to collect license fees to cover the cost of the program. Currently the law provides registration requirements for market agencies and dealers, but there is no authority for collection of licensing fees. The law currently provides for suspension of registrations of market agencies and dealers for violations of the P&S Act. The proposed legislation would no longer require registration of market agencies and dealers but would require a license to operate. The license could be suspended which would have the same effect as the suspension of a registration under current law.

There are currently 9,400 market agencies and dealers registered that would be subject to the licensing requirements.

In addition, there are 1,450 stockyards, 6,500 slaughtering and processing packers, 275 poultry processors, and 6,900 meat distributors, brokers, and dealers subject to the P&S Act that would be subject to the licensing requirements, but would not be subject to having their license suspended. This would be consistent with current law which does not provide for registration of these operations which are not, therefore, subject to suspension.

Our proposed amendments are not being offered to in any way extend regulatory jurisdiction or to provide additional penalties for violations of the P&S Act, but are only to provide authority to collect license fees to cover the cost of the program.

The Omnibus Budget Reconciliation Act (OBRA) requires that all revenue and direct spending legislation meet a pay-as-you-go requirement. That is, no such bill should result in an increase in the deficit; and if it does, it must trigger a sequester if it is not fully offset. Offsetting collections in this bill would recover costs of services provided, resulting in a net zero PAYGO effect. Thus, considered alone, this bill meets the pay-as-you-go requirement of OBRA.

In fiscal year 1995, appropriations action, authorized by this draft bill, would result in the collection of \$8.6 million in licensing fees to cover the costs associated with administering the P&S Act.

The Office of Management and Budget advises that enactment of this proposed legislation would be in accord with the President's program.

A similar letter is being sent to the Speaker of the House of Representatives.

Sincerely,

(SIGNED) MIKE ESPY,
Secretary.

Enclosure

A Bill

To amend the Packers and Stockyards Act, 1921, to provide authority to collect license fees to cover the cost of the program.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. Short Title.

This Act may be cited as the "Packers and Stockyards Licensing Fee Act of 1994."

SEC. 2. Stockyard Dealers and Market Agencies; License Required; Suspension.

(a) Section 303 of the Packers and Stockyards Act, 1921 (7 U.S.C. 203), is amended in clause (2) by striking "he has registered with the Secretary, under such rules and regulations as the Secretary may prescribe, his name and address, the character of business in which he is engaged, and the kinds of stockyards services, if any, which he furnishes at such stockyard. . Every other person operating as a market agency or dealer as defined in section 301 of this Act may be required to register in such manner as the Secretary may prescribe. Whoever violates the provisions of this section shall be liable to a penalty of not more than \$500 for each such offense and not more than \$25 for each day it continues, which shall accrue to the United States and may be recovered in a civil action brought by the United States." and inserting "such person has a valid license as provided in section 414 of this Act."

(b) The first sentence in the eleventh undesignated paragraph under the heading "Marketing Service" of the Department of Agriculture Appropriation Act, 1944, 57 Stat. 422, as amended, (7 U.S.C. 204) is amended by striking the word "registrant" the first time it appears and inserting in lieu thereof "market agency or dealer"; and by striking the words "such registrant" and inserting in lieu thereof "the license of such market agency or dealer".

SEC. 3. Licensing of Packers, Live Poultry Dealers, Stockyard Owners, Market Agencies, and Dealers; Penalties; License Fees.

The Packers and Stockyards Act, 1921 (7 U.S.C. 181 et seq.), is amended by redesignating sections 414 and 415 as sections 416 and 417, respectively, and by inserting after section 413 (7 U.S.C. 228b-4) the following:

"SEC. 414. (a) No person shall at any time be engaged in the business of a packer, live poultry dealer, stockyard owner, market agency or dealer without a license valid and effective at such time. Any person who violates any provision of this subsection shall be liable to a penalty of not more than \$500 for each such offense and not more than \$25 for each day it continues, which shall accrue to the United States and may be recovered in a civil suit brought by the United States. Any person violating this provision may, upon a showing satisfactory to the Secretary of Agriculture, or the Secretary's authorized representative, that such violation was not willful but was due to inadvertence, be permitted by the Secretary, or such representative, to settle such person's liability in the matter by the payment of fees due

for the period covered by such violation and an additional sum to be fixed by the Secretary of Agriculture or the Secretary's authorized representative. Such payment shall be deposited in the Treasury of the United States in the same manner as regular license fees.

"(b) Any person desiring any such license shall make application to the Secretary, under such rules and regulations as the Secretary may prescribe. The Secretary may by regulation prescribe the information to be contained in such application and to be furnished thereafter. Upon the filing of the application, and annually thereafter, the applicant shall pay such fee as the Secretary determines necessary to meet the reasonably anticipated expenses for administering this Act. Such fees and late payment penalties shall be deposited in the Treasury of the United States and credited to the accounts that incur the cost of providing services. In fiscal year 1995 only, such fees shall be collected and available only to the extent provided in advance in appropriations acts and are authorized to be appropriated to remain available until expended. In fiscal year 1996 and thereafter, such fees and late payment penalties may be collected as authorized by this Act and shall be available until expended without further provision in appropriations acts: *Provided*, That financial statements prescribed by the Director of the Office of Management and Budget for the last completed fiscal year, and as estimated for the current and ensuing fiscal years, shall be included in the budget as submitted to the Congress annually. The Secretary shall give public notice of any increase to be made in the annual fee

prescribed by the Secretary hereunder and shall allow a reasonable time prior to the effective date of such increase for interested persons to file their views on or objections to such increase.

"SEC. 415. (a) Whenever an applicant has paid the prescribed fee the Secretary, except as provided elsewhere in this Act, shall issue to such applicant a license, which shall entitle the licensee to do business unless and until it is suspended by the Secretary in accordance with the provisions of this Act, but said license shall automatically terminate on any anniversary date thereof unless the annual fee has been paid: *Provided*, That notice of the necessity of paying the annual fee shall be mailed at least 30 days before the anniversary date: *Provided further*, That if the annual fee is not paid by the anniversary date the licensee may obtain a renewal of that license at any time within 30 days by paying the fee plus \$25 which shall be deposited in the Treasury of the United States as provided for by section 414 of this Act.

"(b) The Secretary shall refuse to issue a license to an applicant if the Secretary finds that the applicant is a person who has a license currently under suspension; who fails to meet the requirements for licensing as set forth in the Act and regulations prescribed by the Secretary; or who is found, after opportunity for hearing, to be unfit to engage in the activity for which application has been made."

SEC. 4. Effective Date.

The provisions of this Act shall become effective upon October 1, 1994.

Section-by-Section Analysis

Section 1

Short title "P&S Licensing Fee Act of 1994"

Section 2

All market agencies and dealers are required to have a valid license to operate at all stockyards posted under the provisions of the Packers and Stockyards Act (P&S Act). Registration will no longer be required. Registration requirement is replaced by license requirement.

The license of a market agency or dealer may be suspended for insolvency or violation of any provisions of the P&S Act.

Section 3

All packers, live poultry dealers, stockyard owners, market agencies, and dealers as defined in the P&S Act and operating subject to the P&S Act are required to have a valid license.

A penalty of not more than \$500 for each offense and not more than \$25 for each day it continues is provided for operating without a valid license.

Any person desiring a license to operate subject to the P&S Act is required to make application for such license. The Secretary may prescribe the rules and regulations under which applications may be made.

Fees collected in FY 1996 and thereafter will be deposited in the Treasury and remain available, without further appropriation, to cover the expenses for the administration of the P&S Act. In FY 1995, the collection and use of fees are subject to appropriations.

The Secretary is required to give public notice of any increase to be made in the annual fee and shall allow a reasonable time for interested parties to comment.

The Secretary issues a license when an applicant pays the prescribed fee. The license entitles the licensee to do business unless and until such license has been suspended.

License automatically terminates unless the annual fee has been paid.

Notice of the annual fee must be mailed at least 30 days before the anniversary date. Late fee is provided if annual fee is not paid on time.

Conditions under which a license shall be refused are set forth.

ADMINISTRATION'S PROPOSED LEGISLATION ON MEAT AND POULTRY INSPECTION

FRIDAY, AUGUST 12, 1994

U.S. SENATE,
SUBCOMMITTEE ON AGRICULTURAL RESEARCH,
CONSERVATION, FORESTRY, AND GENERAL LEGISLATION, OF
THE COMMITTEE ON AGRICULTURE, NUTRITION, AND
FORESTRY,
Washington, DC.

The subcommittee met, pursuant to notice, at 8:33 a.m., in room 628, Dirksen Senate Office Building, Hon. Thomas A. Daschle presiding.

Present or submitting a statement: Senators Daschle, Kerrey, and Craig.

STATEMENT OF HON. THOMAS A. DASCHLE, A U.S. SENATOR FROM SOUTH DAKOTA

Senator DASCHLE. The hearing will come to order.

The purpose of the hearing today, of course, is to review the administration's progress in writing legislation to improve the safety of our Nation's meat and poultry supply. The issue of food safety has been of great concern to this subcommittee over many years. Our focus on meat and poultry safety has intensified since the tragic outbreak of *E. coli* that struck over 500 people, mostly children, in the Northwest in early 1993.

In a hearing in this subcommittee during that outbreak, the administration proposed an ambitious 2-track plan to reform the Federal meat and poultry inspection system and address the problems of microbial contamination. Witnesses from the Department of Agriculture presented an impressive list of reforms as part of the short-term track-1 phase of this plan. We were told that many of these track-1 reforms could be made within 1 year and all within 2 years, but that statutory change may be needed before the improvements could be implemented.

In a series of subsequent hearings in both Houses of Congress, Department officials again spoke of the need for legislation to give the administration the authority it needs to address wide-ranging food safety issues throughout the food production process, from farm to table.

It is now 18 months since the outbreak in the Northwest that resulted in the deaths of four children and still we do not have the legislation that we were promised, legislation needed to modernize the inspection system and prevent future outbreaks from occurring.

My colleagues on this subcommittee have been extremely patient with the ongoing delays, but for many people, time has already run out. Since the beginning of June for this year, the Centers for Disease Control has reported 16 outbreaks of *E. coli* in 11 States across the country. Let me repeat, 16 outbreaks in the last 10 weeks alone. Fortunately, no deaths have been reported as a result of these recent outbreaks, but the fact is that people all over the country are becoming ill, some very seriously ill, from this disease.

When people become ill from their food, besides the devastating personal effects of illness, something else happens. Consumers lose confidence in the products that they purchase, and when consumers lose confidence, producers lose customers. I know that no one in this room wants to see either of these things happen.

We could be just one disaster away from another widespread outbreak such as the one 18 months ago. Unless we act now to prevent future outbreaks, we will continue to play Russian roulette with the health of American consumers and the livelihoods of our livestock producers. We simply cannot afford to delay the reform process any longer.

I fully understand that no bill that we could introduce right now will provide a perfect, comprehensive solution to every problem associated with the safety of meat and poultry products. The problems are complex, and some issues require more scientific research and continued dialogue before they can be resolved.

The fact that we don't have the perfect solution, however, should not be used as an excuse to delay improvements that can be easily implemented now. Certainly 18 months is enough time to identify these reforms that should move forward immediately, the list of statutory changes that are needed to provide the administration with the authority it needs to implement them.

I have heard from numerous groups with a stake in the safety of our food supply, including livestock producers, consumer advocates, industry representatives, and inspectors. As one would expect, there are considerable differences among these groups about the best approach to improving the inspection system. However, there is one thing that everyone agrees upon, that ensuring the safety of our food supply is in everyone's best interest.

With everyone agreeing on that need, a need for a modern, science-based inspection system that deals with the pathogen problem, identifying some reforms that could be made now, should not be such a difficult task. I am not asking for anything that is unreasonable or that is not based on sound science. I am not asking to impose regulations without first consulting with all groups involved to ensure that they are necessary and not unduly burdensome.

I am asking that we simply go ahead with the reforms that make sense to implement right now. For example, we need to assure the public that if contaminated meat is found in the distribution chain, USDA has the authority to recall it. We need to give USDA traceback authority to identify sources of contamination so that problems leading to health hazards can be identified and corrected. We need to extend the USDA's authority to investigate animal diseases, to include animalborne pathogens that can cause disease in humans.

None of these proposed reforms should be particularly controversial or burdensome if we all agree that the safety of our food supply is in everyone's best interest. I want to see such reform legislation passed before the Congress adjourns in October, and I am going to do all in my power to see that that exactly is what happens.

I also want to point out that the proposed bill that we hear about today, is not the first legislative action that has been taken this year to reform the meat, and poultry inspection system. The Senate Agriculture Committee took a significant step toward reform in March, when we included a provision for an independent food safety agency, within USDA, in our bill to reorganize the Department. The new Food Safety Service will provide the framework within which reforms to meat and poultry inspection systems. It can be implemented in an integrated and efficient manner, without interference from other agencies, whose primary responsibility does not include food safety.

If the bill to reorganize the Department of Agriculture is not enacted with this provision intact by Labor Day, I intend to use the administration's legislation as a vehicle to ensure all USDA food safety-related programs are combined into one independent agency within the Department.

This morning, I am pleased to welcome witnesses from the Department of Agriculture. Ms. Patricia Jensen, the Acting Assistant Secretary for Marketing and Inspection Services is here to update us on the administration's legislative proposal. Accompanying Ms. Jensen are Mr. Craig Reed, from the Food Safety and Inspection Service, and Dr. Alex Thierman from the Animal and Plant Health Inspection Service; Dr. Dan Laster from the USDA Agricultural Research Service Laboratory in Clay Center, Nebraska, will also present testimony.

Ms. Jensen, I appreciate the difficulty of the task that you are faced with in developing this legislation. I understand the extraordinary pressures that you continue to have to face. I understand that you will present the main points to be included in the administration proposal, but I sincerely hope that the actual bill will not be far behind.

Other groups will have an opportunity to respond to the administration's testimony and the proposed legislation in a followup to this hearing, after the August recess—should there be one.

[Laughter.]

Senator DASCHLE. Today, the testimony will be only the starting point to the next step in the reform process. As with any bill, there will be debate, there will be input from all affected groups, and there almost certainly will be modifications. Other more controversial reforms may need more time to be worked out.

However, food safety is not an issue that can be addressed today and forgotten tomorrow. The issue is continually evolving, and research will continue to improve our ability to monitor, prevent, and treat many of the current problems. We must keep this in mind so that we don't tie the hands of USDA, and prevent them from using new technologies, as they are developed and proven to solve food safety problems.

If there is one point I want to make again, and again, and again, it is that the process has been stalled long enough. The time to act is now, so let us begin.

With that, let me call upon my colleague and friend from Nebraska, Senator Kerrey, for any opening remarks that he may have.

Good morning, Senator Kerrey.

STATEMENT OF HON. J. ROBERT KERREY, A U.S. SENATOR FROM NEBRASKA

Senator KERREY. Good morning, Mr. Chairman. It is a great day in the neighborhood.

I appreciated, Mr. Chairman, your decision to press ahead with this hearing despite, I say with great respect, the fact that the Department will be coming before us today with, I regret to say, a little more than just hat in hand and not much else.

The last time that we had a hearing, on the May 24, it had a substantial impact upon this country, in that it gave Jay Leno some new material for his monologue. I believe he used the line, there was going to be a new sandwich on the market called a McFecalburger, causing a lot of laughter and causing, as well, a lot of consternation amongst people, at least in Nebraska, where our lives literally depend, as Dr. Laster knows, upon our capacity not just to produce high-quality and safe products; but to do it in an efficient and effective manner.

We are a very competitive industry. It is an international industry. We are finding ourselves competing against an increasing number of people worldwide. Dr. Laster, earlier this year, made a major breakthrough discovery in an animal genome project that, I think, is going to give us the capacity to be even more competitive.

This issue is extremely important for us, and my own view is that while I would prefer USDA be a partner in this effort, I just have to make it clear that I am not prepared to wait incessantly and to say, with great respect, that we have got to get a bill, and that the bill ought not to layer some new system upon an old system, but it ought to be a new system.

The science of inspection has changed, and our attitude towards inspection needs to change. We need to go, in my judgment, from an old environment where we basically sent police people into plants day after day after day inspecting every single carcass that is out there, not as a collaborative effort, not as a gesture to say we are coming into this plant, and we are here to try to help improve the safety and health of this plant; and if you are prepared to be a partner in that effort, you have a good friend. If you are prepared to oppose us, we will be your worst enemy.

It seems to me that we have to have a different attitude towards meat inspection, and use new scientific methods in the inspection effort, and not come in, and just layer a new system on top of the old.

It has been over 18 months since Secretary Espy first came before this committee to fault the present meat and poultry inspection system, and to call for fundamental reforms, and I emphasize fundamental reforms. His appeal was obviously sincere and it was obviously strongly felt. It was, after all, motivated by the deaths of

children. It conveyed a sense of urgency, a need to move quickly and forcefully to implement basic improvements because, in the administration's view, the public health was at risk.

I must say, I have no doubts about the Secretary's continued sincerity on this issue, but it seems to me that the sense of urgency has been greatly diminished. It is gone. How else can we explain these continual delays? The entire situation has raised and sustained consumer concerns about the safety in the meat, and poultry they eat, and publicly maligned the livestock, and poultry industry in the process.

The criticisms, it seems to me, create an obligation on the part of USDA to address these concerns and to address them with force. Either there is a crisis and an urgent need to act or there isn't.

I am not ready to join those who are calling for meat inspection activities to be transferred to the Food and Drug Administration, but I can't help but think, as I watch, delay after delay, on this issue that Dr. Kessler would probably have delivered a bill to us by now. I detect a sense of urgency at FDA, a sense that they are getting on top of issue after issue that I just don't perceive at USDA, at least in this area. I expect I will hear from Secretary Jensen this morning about just how wrong I am, and I hope that is the case.

While part of my concern stems from delays in the process, I must say, I also have concerns about the substance, of what I understand, may or may not be in the Department's evolving legislation. Let me explain. I implied earlier what I am driving at.

At our last hearing on this issue, there seemed to be general agreement expressed around the table that it would be a mistake simply to layer a new, modern, risk-based passive-type inspection system on top of the current antiquated visual inspection system. Some witnesses raised legitimate questions, of course, about whether we are ready to move to a risk-based inspection system. However, there was agreement that the new system, once it is ready, shouldn't be layered upon the old.

The GAO witnesses who testified at that hearing were quite specific with their recommendations on that point. They suggested that current law be changed, so that the Secretary is no longer mandated by statute to order that every carcass, and every bird in every instance, be examined by a Federal inspector, which is the foundation of the old system in place today.

GAO recommended, as they have repeatedly on previous occasions, that the Secretary be given the discretionary authority to impose whatever degree of Federal inspection is deemed essential to protect consumers as the new system, with appropriate safeguard, is brought on-line. GAO also recommended that we give the Secretary the discretion to determine whether every plant has to be visited by every inspector every day. Current law requires such a daily visit.

Yet, I have the impression that such changes in authority are not likely to be proposed by the Department's bill, when we do see it. If that is the case, then it troubles me, because USDA, it seems to me, can't proceed to implement HACCP until the Department comes back to Congress once again to ask for additional statutory changes to allow more discretion on inspection, unless USDA

decides to layer the new system on the old. That could mean, unfortunately, still further delays in getting a HACCP-based system off the ground, and that, to me, means no real advancement and no real progress on the meat safety front.

For that reason, Mr. Chairman, I would hope that this committee will pursue legislation that offers the prospect of fundamental reform rather than the piecemeal nibbling-around-the-edges approach that I fear will be reflected in the Department's bill when we do see it. I don't want to prejudice the bill before it materializes, but I do want to convey my very strong concern on that point.

I intend to raise some additional issues after we hear from the Department and get some questions and answers.

Again, I thank the Secretary, I thank Dr. Laster, and I thank, most of all, you, Mr. Chairman, for pursuing this issue.

Senator DASCHLE. Thank you, Senator Kerrey.

Senator Craig?

STATEMENT OF HON. LARRY E. CRAIG, A U.S. SENATOR FROM IDAHO

Senator CRAIG. Mr. Chairman, let me thank you also for staying with this issue.

Frankly, there is not a great deal more I need to say. It sounds like a very loud and clear voice being sent to this administration. Let me say that that voice is a bipartisan voice that demands of you the rekindling of the sense of urgency that you displayed some months ago.

I think you know what has happened on the industry side of the equation. They rushed very quickly to put in place project and program to evaluate and to measure where they could go and how they could get there and how they could produce a safer product under a HACCP-based approach. Those programs are nearly completed. They have done an excellent job looking at themselves, and from what I understand, they are ready to go.

What I don't believe we find is that the Government-side of that equation, which plays an important role in it, is ready to go.

Let me also echo only one caution that my colleague from Nebraska only treaded lightly across. If USDA by default gives up the responsibility of food inspection to FDA, we will rue the day. You have a long history of playing an important role in this process. Now get on with the business of becoming modern. Get on with the business of moving with industry in a cooperative fashion to produce an increased-quality product in a way that we can rest assured that we have limited the risk even more than we have currently worked to limit it.

I think that is what we have to get at, and we have to get at it quickly.

Senator DASCHLE. Thank you, Senator Craig.

With that, Ms. Jensen, welcome.

[Laughter.]

STATEMENT OF PATRICIA JENSEN, ACTING ASSISTANT SECRETARY FOR MARKETING AND INSPECTION SERVICES, U.S. DEPARTMENT OF AGRICULTURE, WASHINGTON, DC.; ACCOMPANIED BY CRAIG REED, DEPUTY ADMINISTRATOR FOR INSPECTION OPERATIONS, FOOD SAFETY AND INSPECTION SERVICE, U.S. DEPARTMENT OF AGRICULTURE, WASHINGTON, DC., AND DR. ALEX THIERMAN, ACTING DEPUTY ASSISTANT SECRETARY FOR MARKETING AND INSPECTION SERVICES, U.S. DEPARTMENT OF AGRICULTURE, WASHINGTON, DC.

Ms. JENSEN. Thank you, Mr. Chairman.

I still will say it is a pleasure to be here this morning and to be here with Dr. Dan Laster, who is our Director of the U.S. Meat Animal Research Center in Clay Center, Nebraska.

I am here to discuss the legislative proposal the Department of Agriculture is currently preparing to send to Congress for approval. The proposal is just one component of the Secretary's continuing, aggressive efforts to reform the meat and poultry inspection system.

The purpose of this legislative proposal is to extend the authority of the Secretary of Agriculture in a number of areas beyond what he currently has. The additional authorities reflect Secretary Espy's and my commitment to improving food safety from farm to the table and will provide increased public health protection by reducing foodborne pathogens in meat and poultry products and by improving animal health.

As you know, Mr. Chairman, Secretary Espy recently appointed Mike Taylor of the Food and Drug Administration, FDA, to serve as Administrator of the Food Safety and Inspection Service, one of the agencies that I oversee. Secretary Espy and I welcome the arrival of Mr. Taylor. He will bring valuable experience with food safety issues to USDA. Secretary Espy and I look forward to having him join in our team effort at reform.

The Department has been developing pathogen-reduction legislation for some time. This process has been a multiagency effort because the safety of the food supply is a responsibility which is shared by the Animal and Plant Health Inspection Service, the Food Safety and Inspection Service, and Agricultural Marketing Service, Packers and Stockyards Administration, Extension Service, and FDA.

It was also essential that in developing this legislative proposal, full consideration be given to the many concerns and questions raised by stakeholders, such as consumer groups, industry, producers, and employee unions. To ensure development of a comprehensive, effective plan, the Department has worked very hard to ensure the participation and interaction of all interests. It is through public input and the ideas, concerns, and suggestions that that input generates that our objectives can be effectively achieved.

In this regard, very recently, as the Department approached what we thought to be the conclusion of our process, with a draft proposal near closure, we held a series of meetings with representatives of consumer, industry, producer, employee unions, officials of the FDA, and House and Senate staff to explain the basic elements and objectives of our draft legislative proposal. This series

of meetings provided us with new information and prompted us to reconsider a number of important issues.

In addition, all of the groups, including many of the House and Senate Agriculture Committee staff members who attended our Hill briefings, expressed a strong desire to continue working closely with us as we further refine and develop this legislative proposal.

Such statutory changes will compliment the wide range of ongoing initiatives we have already instituted under current law to protect public health. These other initiatives include the strict enforcement of zero tolerance policies, the implementation of a HACCP program, the mandating of safe cooking and handling labels, and the development of a microbial rapid test for use in plants, which Dr. Laster will testify about today. He has already provided me with a brief update on the status of the rapid test. I will leave it to him to tell you all he knows when he testifies.

I would like to now discuss the six principles of the Department's pathogen reduction proposal.

The first principle is, of course, pathogen reduction. We want the Secretary to be required to, number one, limit the presence of pathogens in livestock and poultry at the time they are presented for slaughter. Also, control the presence and growth of pathogens on carcasses and meat and poultry products prepared in any official establishment.

We also want to ensure that all ready-to-eat meat and poultry products prepared in any official establishment are free of food-borne pathogens and ensure that raw or partially-cooked meat and poultry products prepared at any official establishment are labeled with instructions for handling and preparation for consumption.

We intend that meat and poultry products that do not comply with FSIS regulations should be considered adulterated or misbranded. Processors would be given the opportunity to reprocess adulterated products if reprocessing will result in a safe product. Processors would be given the opportunity to label properly if the product is misbranded.

The second principle, I would like to discuss, is mandatory recall. Although the meat and poultry industries have been willing to recall products voluntarily, we believe, the authority to recall products, which pose a threat to human health, is the most fundamental authority a Secretary should possess. Our proposal includes a mandatory recall provision which would be used only when firms decline to recall products voluntarily.

The third principle is traceback. We want the Secretary to be able to require producers and handlers to maintain records to trace the purchase and sale of food animals as far back as necessary. These same records could also be an important epidemiological resource for all of us.

Some producer groups have pointed out to us that they already keep records as part of their quality assurance programs that will be useful to USDA in conducting tracebacks. To the extent that we can rely on these records, we will do so in lieu of imposing duplicative Federal requirements. We also intend to make use of records that we currently require under other USDA programs.

The fourth principle is withdrawal or refusal of inspection. We want the Secretary to be authorized to withdraw or refuse to pro-

vide inspection service for repeated and significant safety violations. Such authority would assure that operations who are unwilling or unable to correct food safety violations would not be permitted to produce meat or poultry products.

The fifth principle is civil penalties. Effective enforcement of inspection laws would be assured by providing the Secretary with authority to assess civil penalties. Enforcement measures would then range from a written reprimand to fines of not more than \$100,000 per incident per day.

The sixth principle is redefining disease in animal quarantine laws. The Secretary is not currently authorized to take regulatory action to protect public health under the animal quarantine laws unless the disease is communicable from one animal to another. We are considering changes to the animal quarantine laws to eliminate this gap in the Secretary's ability to protect human health.

Specifically, the term "disease" would be defined to include any infectious and non-infectious disease and any other health-related condition that may be transmitted by livestock or poultry to other animals or to humans. This definition will authorize the Secretary to take regulatory action to eliminate pathogens and residues in live animals when such action is necessary to protect the health of other animals or of humans.

In conclusion, Mr. Chairman, and Members of the subcommittee, this ends my remarks on the new legislative proposal we are currently preparing for Congressional review and approval. I very much appreciate the opportunity to speak to you today about changes, we believe, are very necessary to strengthen our role in the area of public health.

We will be meeting again with consumer groups, producer groups, industry groups, employee unions, House, and Senate staff members to continue to refine this proposal over your possible recess period. I look forward to discussing this with you further.

I want to thank you, and I will be happy to answer your questions and, of course, to respond to any of your comments.

Senator DASCHLE. Thank you, Ms. Jensen.

Before I turn to Dr. Laster, you have outlined what the proposal contains but you haven't indicated when we will see it. Tell us when we can expect to see a bill in writing.

Ms. JENSEN. We have a commitment to have this bill in writing to you when you return from recess in September, and hopefully we will be able to provide it in late August so that your staff will have an opportunity to review it.

Senator DASCHLE. So by the end of this month, you hope to have a bill to us, is that correct?

Ms. JENSEN. That is our commitment. We have also made a commitment to consumer, industry, producer, union groups to have a technical meeting with them before we send in for final approval that bill, and we will, of course, comply with that commitment. Our goal is to have it done by the end of August and certainly by the time you return, yes.

Senator DASCHLE. Dr. Laster?

STATEMENT OF DR. DAN LASTER, DIRECTOR, U.S. MEAT ANIMAL RESEARCH CENTER, AGRICULTURAL RESEARCH SERVICE, U.S. DEPARTMENT OF AGRICULTURE, CLAY CENTER, NEBRASKA

Dr. LASTER. Thank you, Mr. Chairman, and Members of the committee. I am pleased to be here today.

Secretary Espy and his top staff in this area, Pat Jensen and Mike Taylor, are committed to implementing a science and risk-based food safety and inspection system. As a career scientist and director of the U.S. Meat Animal Research Center, my testimony and any comments will relate and be directed toward our development of a rapid bacterial test and related work in the area for both meat and poultry.

During the past year-and-a-half, Secretary Espy has directed us to accelerate our efforts to develop these rapid bacterial tests. In recent weeks, both the Secretary himself and Acting Assistant Secretary Jensen visited the Research Center and saw a demonstration of how the test will work.

We are well along with the generic bacterial tests for beef and pork. There are some questions that need to be answered before this test goes into plants, either from an industry quality control program or a government regulatory program, but we can safely say that we have demonstrated that the test will work for beef and pork carcasses in a slaughter plant. We are also moving ahead very aggressively on a generic test for poultry and we expect to have these results done within the next few weeks.

The test for generic bacteria is only a first, but we think a very important, step in the Department's ongoing efforts to improve sanitation procedures and to aid in the reduction of bacterial levels as a result of fecal contamination for meat and poultry carcasses.

This test will allow the testing of meat and poultry carcasses on a near real-time basis to monitor the quality control process. Most foodborne pathogens, as I am sure this committee recognizes, that are found on carcasses in processing plants, including *Salmonella* and *E. coli*, come from fecal contamination or as a result of fecal contamination. In other words, of foodborne pathogens, the source is fecal material.

Our objective, at this point, is to provide the technology and research information to help reduce the level of bacterial contamination on meat and poultry, as low as is reasonably possible or feasible. These rapid tests would test for generic bacteria, not pathogens, so it is the relationship we are talking about.

People have made the comment that the correlation, the statistical correlation is low, and my response always has been, and nobody refutes that and I think everybody recognizes it is true, is that although it is low, it is always positive. If you have truly zero fecal contamination on the product or keep the fecal material off, you will have zero pathogens at that stage in the process.

We were able to develop this test by modifying tests that are being used and have been used for a number of years in the pharmaceutical industry, cheese industry, beer industry, and other areas, and they have been using it to assure sanitation. In fact, for the last year or 2, this same kind of test is used in a couple of packing plants in the country as part of their sanitation program.

All our scientists did was to adapt the use of the test on the meat, and what that means is separating out the bacteria. Basically, without going into too much detail, it measures microbial ATP, which is the relationship between ATP, whether it is in the cells of your body or a bacterium, the relationship between ATP and the number of bacteria in this case is constant. So ATP is the storage form of energy in cells. In less than 5 minutes, the test will provide an accurate and repeatable method to detect relatively high levels of generic bacteria on beef and pork, compared to the 48-hour plate test.

Beef carcasses in a packing plant, based on our measures, that have had no contaminated and tested within 45 seconds of hide removal have near zero levels of bacteria, while carcasses with visible fecal contamination average about 100,000 bacteria per square centimeter or 5 logs, 5 zeroes, and ranges from 10,000 to roughly 10,000,000 bacteria per square centimeter of carcass area.

While this test will not accurately predict from zero to millions, it is adequate, we think, and so do many sectors of the industry, adequate to monitor the process by testing the product.

Although progress may seem slow, and I know it does to us in all areas, I am confident that we are moving very rapidly and that these tests, as I say, will be available for potential industry use and government regulators in the near future, within a few weeks.

Although the test is rapid, it is not a perfect test nor will it be a perfect answer, and I think everybody who is dealing with it recognizes some limitations but certainly recognizes the benefit that it can be useful.

I have seen, along the same lines, some comments that trimming the so-called zero-fecal policy, that trimming visible fecal contamination, on beef carcasses, causes more bacterial contamination than not trimming. I know of no comparative research, or national survey data to document that—and we have from our Center—data that indicates that trimming and washing, will substantially reduce bacterial contamination by simply washing all over with tap water; because it is very well known that, washing with tap water reduces fecal contamination only log 1 to 2, 1 or 2 zeroes per square centimeter.

There has been a lot of information written and discussed on different intervention procedures for both meat and poultry, but in beef, for example, whether fecal contamination is removed by trimming and washing with tap water, which is being done now, washing with hot water only, or trimming and washing with hot water, which we think in the near term is the most likely to come out of the results, there is no way to assure the quality control process is working properly to minimize high levels of bacteria unless we have some type of rapid bacterial test.

The rapid test that we have developed, or rather modified, will provide an essential tool for both meat and poultry.

Based on my direct contacts with leaders of the meat and poultry processing industry, and we have worked with a number over the past couple or months, or the past year, these industries are more than willing to implement these new technologies to help improve the safety of their product, and it is their product, we fully recognize, not a product of the Government.

As a career employee, my job is research. I am fully confident that Secretary Espy will move forward very decisively, and vigorously, as soon as we have scientifically-sound research information that document these bacterial tests and intervention treatments that are being developed, can be used effectively; and we expect to have these results provided to him within a very short period of time.

Thank you very much. I will try to answer any questions that you may have.

Senator DASCHLE. Dr. Laster, your definition of short period of time and mine may be different.

I must tell you, I get increasingly frustrated. I noticed that you corrected yourself when you made reference to the last couple of months, and then you had to say, I guess it was over a year or so. I am very interested in what you are doing, but I am also interested in knowing when we can take what you are doing and begin to implement it.

I must say, I am becoming increasingly frustrated with the inability to be confident that at some point, as you say, in the not-too-distant future, we can implement the results of this information and use it in scientific tests.

So tell us now, when can we expect to use the results of your information in scientific tests? When can we implement them?

Dr. LASTER. We are using them in scientific tests now and we are testing them in the plant. You mean when can we use them in regulatory programs?

Senator DASCHLE. That is right.

Dr. LASTER. Or when can we move forward?

Senator DASCHLE. That is what I am asking, is when will we have this information available to us to implement them in a regulatory format.

Dr. LASTER. I was asked that question just 2 or 3 weeks ago, in a very similar manner, from Secretary Espy, and I said within a few weeks. He said, do you want to give me a date? I said, I will give you a date just as soon as we have the research done; but a few weeks, in the process we are going, Mr. Chairman, I think is—and a few weeks, to me, doesn't mean months and years, but whether it is 3 weeks or 6 weeks or 7, we will have it as soon as we can. We have been going for a long time with the scientists in bringing the information on-stream.

I know you and a lot of people are impatient, but we simply can't give the answer until we complete the data, and they are collecting this data, as they say in this town, as we speak, on poultry. So we are near an end to being able to document not only will it work on beef and pork.

As companies move forward, there will be continuous questions, and they are the kind of questions that can be answered as it moves forward. You have a test and you go into a plant, the kind of questions we are looking at now in beef, for example, is not will the test work on beef adequately for a cut-off point that we think would be reasonable, but rather do you have to do plate counts for each and every plant or can you use the adjustment factors from the plants that have slaughter beef or cows and calves. So those are questions that we are continuing to answer as fast as we can.

Senator DASCHLE. As you indicated——

Dr. LASTER. Again, I am saying a few weeks, not months or years. A few weeks to me certainly means having those things done well before the end of this year, and probably before you all get through with this legislation.

Senator DASCHLE. That is why I say your definition of time and mine are different. You just indicated a few weeks, and then in the same breath you said it could be before the end of this year.

Dr. LASTER. I said it would be.

Senator DASCHLE. There is a difference between a few weeks and a few months. Before the end of this year, we are talking months, and every time I hear somebody come before this subcommittee and say months, then I start thinking years.

I must tell you, I am not satisfied with that answer. I really hope that you can provide the final material that allows us to begin implementation in a few weeks, and by a few weeks, I am talking about the end of September at the latest, because then you are getting into a few months. There is absolutely no reason why we can't come to some conclusion on this, after all of the delay, all of the incredible reason given daily, weekly, monthly for the fact that we still don't have the information necessary to begin action.

We just can't accept the incessant delays that we get, and I hope that a few weeks actually for the first time may mean a few weeks, which would be, for me, the end of September. Can we agree that perhaps the end of September would be a reasonable timeframe, or are we indeed talking about then a few months?

Dr. LASTER. We are not talking about the preparation of a paper that says, here is our policy. We are talking about getting biological and physical results. I can't guarantee that the validation of the work that is going on this week on poultry is going to give us the answer. That is why we call it science and getting the information. This is not a made-up area.

So far, my credibility has been very good, I think, with the Secretary because we haven't made promises we couldn't keep. We told him earlier that we would have beef and we would have pork and we ran into some problems with poultry. We think we have got it. We are very optimistic at this point.

I can't give you, him, or the world, an answer that says by September 15, we will provide it to you. We will provide you an update at that point. We may be able to provide it, within the next 3 weeks, that says, "Yes, it will work in poultry."

I can't tell you that, Mr. Chairman, until you know what the results are. We can't manufacture results.

Senator KERREY. Mr. Chairman?

Senator DASCHLE. Senator Kerrey?

Senator KERREY. I might just add, one of the problems, it seems to me, that you are having here, Dan, is that you have to provide scientific information and it is virtually impossible to do it in the time required——

Dr. LASTER. We are doing the best we can.

Senator KERREY. The reason this is happening is that we are presuming, as I hear it, the continuation of a rigid command and control system of regulation. That is what I hear. If you presume that that is going to be the case, and I see some squirming

and saying that is not going to be the case, but I must tell you, I hear that the problem is we have to give the Federal Government more power to promulgate regulations for pathogen reduction, we give them more power for recalls that are going to become mandatory, more power for requiring record keeping, more power to withdraw and refuse inspections, more power to impose penalties, more power to define disease.

You referenced it several times, you brought the employee union in here. I must tell you, I hear this thing being driven by concerns about inspectors keeping the *status quo*, and if you keep the *status quo*, Dan, you are going to constantly be in a situation where we have to make a scientific decision and insert it into an old regulatory mechanism and it just doesn't work. That is the problem.

You can't go into a plant and bring new science into that plant if you have an old command-driven system that requires you to make a scientific decision, insert that into a process, and then give basically your policeman authority to go out and carry it out under the terms and conditions of whatever your scientific conclusion is.

Dr. LASTER. Let me respond. I honestly do not know if the use of bacterial tests, that we are developing, requires new laws or not. What I am addressing, is saying to you, within a few weeks, is that we will be able to say to the Secretary, "We are comfortable now that we have the documentation that this test, which can be done in less than 5 minutes, as opposed to 48 hours, will work in measuring bacterial levels on poultry, beef, and pork."—that is what I am talking about, not—

Senator DASCHLE. Did I hear you say earlier, though, that it was poultry that was holding you up? If that is the case, is it possible to move ahead with pork and beef?

Dr. LASTER. We are getting the same information for all three of the species and we just completed a validation trial, the second one with beef, last week. We will complete a trial on Sunday of this week, our scientists will. When we get those kind of results, we will know where we are at this point in time. That is as good as we can do.

We worked on our beef, 50 percent of our research. We started on beef, and then we started on pork and poultry. There were some problems in getting poultry and our scientists are working on it, but we are getting it done.

Senator CRAIG. Mr. Chairman?

Senator DASCHLE. Yes, Senator Craig?

Senator CRAIG. When you were talking about fecal material and washing and all of that, you never once mentioned acid wash, which appears to be working in certain test areas. We are very concerned. We heard testimony here, some months ago, that said trimming spread fecal matter and created greater bacteria on carcasses.

Dr. LASTER. I would challenge that.

Senator CRAIG. I wish you would, because it came from very credible sources. It appears that one of the things I think we are all frustrated about is getting in lockstep here and denying ourselves the flexibility to look at some alternatives that are good for the product and good for the industry in being able to produce the product.

One of them that has been discussed at length, at least in the information I have, it has not been effectively refuted yet or refuted at all, is the idea of using an acid wash to knock the bacteria down.

Dr. LASTER. One of the problems, Mr. Craig, with using acid, and we have data on washing, is acid, acetic acid and other similar acids at low levels, one to three percent, will not kill *E. coli* 0157:H7 on beef carcasses. We documented that within 6 or 8 weeks after the outbreak in Washington. It will kill *Salmonella* and some other pathogens. It will, in fact, kill *Salmonella* at low levels, but it will not kill 0157:H7, the acid.

Senator CRAIG. I did not hear you say that your quick test or your rapid microbiology kind of test would detect *E. coli* bacteria. You said it would detect bacteria in the generic form.

Dr. LASTER. There are two subjects here, two subjects that you have addressed. One is the use of acid or hot water or trimming as an intervention procedure and the other one is testing to see if those procedures, and using a bacterial test as opposed to visual observation that has been going on for 70 years or however long, to see if the process is, in fact, getting the bacteria off.

Once you get fecal material on a carcass and bacteria gets there, then it is very difficult to remove. So it is——

Senator CRAIG. So you are suggesting not only that you are developing the test, are you stepping in front of that and saying there needs to be a different handling procedure that creates less risk of fecal bacteria on carcasses to begin with?

Dr. LASTER. Yes, but I am saying the two issues are separate. One is an intervention procedure——

Senator CRAIG. I understand.

Dr. LASTER. It is not a matter of testing versus washing or something. It is a matter of using a test to verify that the washing is, in fact, reducing to very low levels of bacteria once it gets on the carcass.

Senator CRAIG. So my question specific to you is that the rapid microbiological test that you are perfecting, this 45-second——

Dr. LASTER. No, 5-second.

Senator CRAIG. Five-second?

Dr. LASTER. Five-minute, I am sorry.

Senator CRAIG. Five-minute, all right.

Dr. LASTER. Five-minute. Sorry.

Senator CRAIG. What information does it give us? What do you expect it to be able to give us?

Dr. LASTER. What it will give you is the level of generic bacteria per square centimeter on the carcass, which is a very good indication of either you have kept the fecal contamination off the carcass, or that you have been able to either trim or wash off most of the bacteria levels that got on there—good and bad bacteria.

Senator CRAIG. At that point, the test has shown bacteria, what do we do at that point? Do we dump the carcass or do we take a meat that could be cooked or processed and destroy the bacteria so it is very edible, or do we toss it away? Where are we at that point? If you have made the determination, what do you do at that point? Do you go back to a wash? Do you go back to a trim?

Dr. LASTER. One of the things that has not been finalized, but certainly I think it should be finalized based on the data, is at

what level do you call it a threshold and say that the process is not working adequately. An analysis of our data is if you look at visible fecal contamination on a carcass, you can see the fecal material—first, if there is no contamination and you sample it within 45 seconds on the kill floor, it is near zero levels of bacteria.

If you can see visible contamination, you have from 10,000 to 10,000,000, roughly, or more, bacteria per square centimeter from the fecal material that was on there, and in some cases—that level. The average is log 5 or 100,000, but the range is what I just said.

So if, in fact, you are looking at visible fecal contamination and you know you have measured that, and we have, that it ranges from 10,000 and up for the most part, that is an obvious place to say that that is a threshold. We need to make sure the process is working.

Part of the question and concerns have been, and I am sure have been raised with you, is if you find a carcass that has 7,000,000 bacteria, whether they are good or bad, you don't know, but you know it has been fecally contaminated, then do you reclean it or do you say, well, we will do it later?

I know of no company, and I deal with a lot of companies, is going to let go out the door a carcass that had 10,000,000 bacteria that was tested—I am not talking about anything other than tested—and put themselves at risk.

Senator CRAIG. I agree.

Dr. LASTER. So the answer to your question is, of the carcasses you test, I would say—you had better reclean it and retest it in that case.

However, for the most part, and I think it has been somewhat misstated at times or a misperception or whatever, for the most part, beef, for example, and the other products, are clean. We are not talking about all the carcasses going through as having a problem today. We are talking about 5, 6, 7 percent and working on those to help assure that they are not contaminated.

Senator CRAIG. Thank you for saying that. That is an important point to be made.

Dr. LASTER. The other thing, along the same line, is it is virtually impossible to convert live animals to meat and not have some level of contamination, but the use of a test to see what will improve or not improve, if you are using hot water, and I am a big fan of hot water because hot water will kill *E. coli*, to trim carcasses will kill *E. coli* and many of these other treatments will not.

So what I am concerned about, with the industry, and others is that the expectation, at this point in time, is that the industry says the packers are wanting to trim our carcasses, and we are having to pay for it; and we want to stop trimming. We want to use hot water. They haven't looked at all the facts. The facts are that hot water will remove no more probably than log 3, 3 zeroes, and some of the carcasses have log 7. It has to be delivered very well at that point. Tap water will remove 1 to 2 logs.

So when we have data to show that here is a level of bacteria and they say the data, well, the data was based upon, I understand, the measurement not of carcasses on a comparative data

but on ground beef on coliform and other forms. It is well down the line. It is not carcasses we were talking about here in this last hearing.

So the industry in the last year-and-a-half, and I am defending the industry, not the Department in this case, have increased the level of use of gloves. They wash the knives. It is kind of a messy process, but I would say the level of sanitation has substantially increased.

The industry is not opposed to bacterial testing, based on my contact with major companies and vice presidents of companies. They are concerned about what the level of bacteria "threshold" is, but a reasonable level is what I just said, at least as a negotiating point.

Senator CRAIG. Mr. Chairman, Doctor, I think the industry is also concerned about developing a process that is predictable, that isn't duplicative, that isn't one stacked upon another, as the Senator from Nebraska spoke to, that develops a level of assurance that is very high as it relates to all this kind of thing.

Mr. Chairman, I will turn it back to you. Thank you.

Senator DASCHLE. Thank you, Senator Craig.

Dr. Laster, you talked about the varying degrees of ranges that are out there already. I think the message is we have to have some standards and we have to be able to hold that data against some standards and we don't have them.

I think the message is, get us the information so we can create the standards and promulgate the regulations that will support those standards. I think there is a growing impatience and a growing frustration on the part of this committee, I am sure on the part of Congress, in the inability to be able to deal with that more forthrightly. That is the message.

Dr. LASTER. We appreciate that very much. We share it with you, Mr. Chairman, very much so. I asked our scientists the same question you asked me is, "When will we have it done?" and I have been very much a part of the process. I just can't promise you or anyone else a date that says, "By this date, we will guarantee that it is there." As soon as we get it, we will provide it, and it will be very soon, within a few weeks. That is the best I can do, in terms of knowing it will work.

Senator DASCHLE. It sounds ominously like the Post Office, but we will give you the benefit of the doubt.

Dr. LASTER. No, no, no.

[Laughter.]

Senator DASCHLE. Ms. Jensen?

Ms. JENSEN. Yes?

Senator DASCHLE. You talked a lot about the proposal and you have given us some assurances this morning now that you can have a bill to us by the end of this month. I think for the record it would be very helpful if you could give us an explanation as to why it has taken this long.

What has caused the delay? What has caused the inability to come to some closure on a draft and therefore the ability for the Congress to move ahead with the legislation?

Ms. JENSEN. Mr. Chairman, I first of all would like to tell you that I do share your frustration in this process. The bureaucracy does seem at times to be quite clumsy, and this would be a good example.

I can give you my personal experience in this, which begins as Acting Assistant Secretary in January and seeing a draft as it had been developed and putting it into the decisionmaking process and having discussions internally with the various agencies, FSIS and APHIS, who were bringing it to us, and then to tell you that there is an established process it goes through within our own agency, and then that it goes to OMB and it goes through other layers of government, if you will, for comment.

As I indicated in my testimony, we felt that we were very close to closure here several weeks ago, at which time it became apparent to us that we needed to spend more time with groups who wanted to know more specifically where we were headed. We said, OK, we will do that. We will take that time.

What we said to one another is it is better to have it right—

Senator DASCHLE. Let me stop you there. Excuse me for interrupting. I hate to do that. Why was there not consultation with groups earlier? Why did it take the confrontation that sort of evolved out of frustration to bring you to that realization?

Would it not have been possible earlier in the process to say, what shall we do? How can we confront these problems? Involve them at that point in a more deliberative and consultive fashion and then come to some conclusions. Would you not have avoided the problem that you had earlier in the summer?

Ms. JENSEN. I think that we would have avoided much of it but not all of it, that in fact, when you are sitting around a table, as we did, for instance, at the HACCP Roundtable and you are discussing elements or philosophies, you can have a different kind of discussion than when you have actually put language on paper.

There is something about that finality of saying, we have been through all of these processes, here is where we are at, we are just about ready to go, and then everyone says, but wait, that isn't what we meant or we didn't have enough input. That occurred, and we stopped the process at that point and said, OK, we will invite you all in. In fact, we are inviting all of those groups in again next week for technical briefings.

I do share your frustration here, but I have a sense of responsibility to have this legislation be in form that has the input and the value of all of these constituencies, stakeholders, I think, is the word that we used, when we come forward, so that when we give this to you, we give you our best shot.

Senator DASCHLE. I appreciate your determination to give us your best shot, but I must tell you, I get increasingly concerned about your credibility and ours, frankly. When the American people see the problems associated, as we have outlined them already this morning, with the food and the industry itself, and see the cumbersome and extraordinarily long process involved in response, that frustration then has a profound effect on the interpretation of your actions; and ultimately your credibility to deal with the issue to begin with.

I think we are perilously close to losing the confidence of the American people when it comes to addressing this issue in a constructive and successful manner, in part because of the incredible delay, in part because of the perception that we simply cannot respond.

So it is not just the issue itself that I am concerned about now. It is our perceived ability to deal with the issue in an effective manner. We have just got to do better than this.

Ms. JENSEN. Mr. Chairman, let me make what I think to be a very crucial point here, and that is that this legislation compliments a system of changes that have been ongoing, that the Secretary has put in place. It will compliment something. It isn't necessary to have this, for instance, to move forward in our discussions on HACCP, and to do what we need to do. It isn't necessary, in order to develop the rapid test, or to place labels on raw meat and poultry. We have made progress in significant areas. This is a piece that compliments that total package.

Senator DASCHLE. I don't want to further belabor the point, but we are getting close to the point where I would look for another name than "rapid test", frankly.

[Laughter.]

Senator DASCHLE. It has been anything but rapid, and I think it is sort of indicative of the entire process. There is nothing rapid about this process at this point. I think we really have to understand the pitfalls of further delay.

I have a number of questions that I want to ask about the proposal itself. You mentioned that you will promulgate regulations that will reduce pathogens. I would like to know more details about it. What sort of regulations do you have in mind to limit pathogens in live animals at the time they are presented for slaughter?

Ms. JENSEN. Mr. Chairman, this is a part of a provision which would mandate that the Secretary, or require the Secretary to respond as science is developed. So what we are saying is that if we develop scientifically a method or have a discovery, that the Secretary is required then to incorporate that into the limiting of pathogens.

Senator DASCHLE. So there is nothing specific with regard to the requirement that we limit pathogens? It is only if the Secretary can develop some criteria, is that what you are saying?

Ms. JENSEN. The operative word here is "require." Currently, the Secretary has the discretion to do whatever the Secretary feels is necessary but is not absolutely required to look at science based in those decisions.

As you know, when you set up a regulatory process, you set up a notice and comment, and it would be very difficult for me to anticipate what discoveries might come along, but we would set up a regulatory process so that there would be notice and comment on specifics as we move into the future of inspection.

Senator DASCHLE. I am anxious to see exactly how you do this. Do you intend to have a timeframe for publishing the regulations?

Ms. JENSEN. That is a comment that was made to us during the discussions with the various groups, and that we are taking a look at just exactly how we could incorporate a timeframe, not

knowing what will come along. We are taking a look at that element within this.

Senator DASCHLE. Do you intend to evaluate the effectiveness of the regulations in reducing pathogens? Is there a method by which that can be achieved?

Ms. JENSEN. That is also one of the comments that has come before us that contains a very good idea. We have looked at some language to do something similar to that.

Senator DASCHLE. I am getting pretty vague answers here to something that I had the impression, just a couple of minutes ago, was in its final form or close to it. Now I am getting, well, we are getting a lot of comments and the Secretary may do this. What is it? Are we still in an early drafting stage here, or do you have specific legislation that deals directly with things of this kind?

Ms. JENSEN. We have specific draft legislation that we have worked on. It just so happens that a couple of the comments that you have just made are areas where there were some strong comments when we met with groups. There are other areas, such as the necessity for traceback, a certain traceback system or record-keeping system, that are more definitive than where we are at.

Senator DASCHLE. I expect that within the next couple of weeks that you will be more definitive in this area as well?

Ms. JENSEN. Yes, Senator. As I had indicated, next week we are going to set up meetings on the technical aspects of what we are pulling together, with our own people responding to questions from industry, from producers, from consumer groups as to the practical application. We see that as the final piece of helping us put that language together.

Senator DASCHLE. You made reference just a minute ago that this will require the Secretary to do certain things. How does it require him to do it, and what specifically are you referring to when you say it will require him to do it? What, if anything, will be required and what will be discretionary under the proposal?

Ms. JENSEN. Mr. Chairman, the requirement is to make these decisions incorporating science and technology into those decisions. The decisions would be limited pathogens and the list that I had given you during my testimony.

As I said, now that is discretionary. The Secretary is not required to employ this science. He can if he or she wants.

Senator DASCHLE. I am not sure I understand. Explain that for me.

Ms. JENSEN. Currently, we have a Secretary who has been very aggressive in the area of using science in the inspection system improvement. That is his choice and his discretion, to set out his program based in that direction.

I am saying that the new language would require a Secretary to look at science and to incorporate that into decisions of the future where inspection of meat and poultry is concerned.

Senator DASCHLE. I am just trying to think, if I am trying to judge that requirement, you just told me that there is a requirement that the Secretary look at science. I have to tell you, that is a strange requirement. I would think that any Secretary would not

have to be required to look at science in making regulations, that that would be just common sense he would want to do something like that.

So what new progress are we making here that is a real indication of some change in determination? The requirement to look at science is a pretty weak requirement. For heaven's sake, there ought to be plenty of opportunities for requirements today for all kinds of considerations, in looking at science, looking at all kinds of data. What is new about that?

Ms. JENSEN. The scientist sitting next to me is asking to respond to that.

Dr. LASTER. I am not familiar with the legislation or the request—

Senator DASCHLE. Why don't you use the microphone there, Dr. Laster.

Dr. LASTER. I am sorry. I am not familiar with the legislation, but one of the things that we are doing and we have done, and I know it sounds slow to you but it is going to come fairly fast—

Senator DASCHLE. Here we go again.

[Laughter.]

Senator DASCHLE. Go ahead.

Dr. LASTER. Adapting some of the technology from biomedical sciences and defense industries will allow us, faster than we would have otherwise, to develop, for example, tests specific for *E. coli* 0157:H7 and *Salmonella*, the eight strains of *Salmonella* that are a problem.

The issue is getting a test and having a monoclonal antibody that will test for them is one thing. How can you effectively use that in the industry? How can you test in a plant? Where do you test in a plant?

Part of that process will come very rapidly, everybody is in a hurry, and as it comes, is there adequate legislation or opportunity to start implementing that, those kinds of tests, not on a mandated national basis but on a test basis but still in plants, going back to, say, the point that you would want to do intervention.

Senator DASCHLE. I would think that that is just something that is done.

Dr. LASTER. Pardon me?

Senator DASCHLE. I can't imagine that there has to be some legal requirement that any public official look at that kind of information and take it into account in promulgating regulations. I mean, that is just done. If it isn't done, no wonder we have the problems we have credibility wise.

I guess my point is, and I don't want to belabor this, but I have to tell you, I don't want to hear lip service and I don't want to hear these generalizations about how great this is going to be if all we are doing is restating the obvious and reinventing the wheel. We are looking for some new ways in which to treat these issues in a more effective manner.

I have to tell you, I am not convinced we are at that point yet. If we have waited this long for this little, I don't think you fully appreciate the consequences in coming back and sharing that with us. I want to be as empathetic and I understand the difficulties, but I must say, there are high expectations and even higher

frustrations with this process so far, and answers like we have just received don't help.

Senator KERREY?

Senator KERREY. Just to reinforce the point, Mr. Chairman, as you recall, Secretary Jensen, you and I had a heated conversation at that May 24 hearing about when the HACCP regulations were going to be issued. I was trying to press for June 15; you said August 1. Are those regulations in place today? Have they been issued?

Ms. JENSEN. No, Senator, they have not. I——

Senator KERREY. When will they be issued?

Ms. JENSEN. They will be issued this fall. I had a conversation——

Senator KERREY. Fall is 3-months long. Fall is a 3-month period of time. It is one of my favorite seasons, but it is a long period of time.

[Laughter.]

Senator KERREY. Ms. Jensen, when will those HACCP regulations—do you understand the problem? Do you know what we are dealing with here?

Ms. JENSEN. Yes, Sir, I do.

Senator KERREY. We can't give meat inspectors the flexibility to do the right thing until we get the HACCP regulations in place. We have to continue with the command, control, regulatory system until we get HACCP out there because the consumer groups don't trust that flexibility. That is why we need HACCP. There is an urgency to get it in place.

I have to tell you, Dr. Kessler would have had it done 60 days ago. So do it or don't give me this: "I am going to get it done in the fall," Ms. Jensen. I appreciate that it is difficult, but you told me August 1 and now it is "in the fall."

Ms. JENSEN. Senator, as I made the point the last time we had this discussion, there is no reason why any industry, meat and poultry industry, could not voluntarily put in place a HACCP program, and in fact, many of them are doing so.

Senator KERREY. Are you supportive of the industry doing this in a voluntary fashion? Is that what you are saying? Your testimony indicated five new command authorities that you are saying USDA needs. Are you an advocate of a voluntary system, Ms. Jensen?

Ms. JENSEN. I am an advocate, Senator, of voluntary measures when we can use them, and in fact, that was one of the major changes in the draft legislation we had. When we talked to producer groups and others, they said, look, on recall, we are voluntarily doing that now. Why are you imposing a mandate? We said, you have a good point there. So we won't do that while you are voluntarily recalling.

I would like to return to HACCP. I would just like for you to understand what has happened. Whether you appreciate it, like it, or agree with it is another thing.

Senator KERREY. You are quite correct. I neither appreciate, like, or agree with it, so you can presume that to begin with.

Ms. JENSEN. What has happened since you and I last spoke is that we have indeed hired a new Administrator for FSIS. That

Administrator and I have had several conversations about HACCP. He is from FDA. He is very, very experienced in HACCP. He believes in HACCP, and I can assure you that that is one of many reasons he is coming to USDA, because we appreciate, we support, we want a strong HACCP program.

I talked to Mike Taylor yesterday and said, I suspect I will get a question from Senator Kerrey about HACCP and why we don't have it yet. He said, I will have it done for you in the fall, but for me to do it then would be——

Senator KERREY. Then why did you tell me at the last hearing that August 1, you would have it done? Where did that date come from? Now you are telling me that I have to have Mike Taylor on board before I can do it.

Ms. JENSEN. No, Senator, I am saying that he requested that we move along into this process with him at the helm, and I have granted him that request.

Senator KERREY. I am going to, unfortunately, Mr. Chairman, not be able to stick through this entire hearing. I have some additional questions that I would ask. I have a bill on the floor that I have to go participate in.

My greatest fear, I must say, and listening to you describe this, is that it is not going to be fundamental change. It is not. What I hear is that you are going to put new paint on an old building. I hear that, Ms. Jensen. I hear your concern that you are trying to resolve all the conflicts, you don't want something that is going to be terribly controversial. You can't resolve them all. Come before us with a piece of legislation that has some controversy attached and you are apt to have the right thing.

We have to change the culture of the examination process. We have to give the inspectors more authority than they have right now to work with the industry, and in order to do that, I have to have HACCP in place as the foundation.

You said earlier, this is one part of lots of other things that are in place, but then you don't have these other things in place. You can't come to us and say, this new bill is just one thing of many things that we are working on. In fact, you haven't done the other things. We have to get HACCP in place and this has to be a fundamental change in the way that we examine so that we can bring new science on line.

Ms. JENSEN. Senator, we do have——

Senator KERREY. When science tells an examiner that here is a way to make this thing work, we ought to have a system that allows that examiner, that health specialist to work with a plant and say, what we are concerned about is health. We are not concerned about satisfying some preexisting regulation that has been established in an environment of distrust. What we are concerned about is outcome. What we are concerned about is producing healthy products. We don't want to have a system that is so darn rigid that when new science comes on line, that we can't put it in place.

What I fear when I hear you asking for additional authority, basically saying, unless we give the Secretary more power, we can't make it work, I hear you heading in a direction of increasing the rigidity of the system. I tell you that because I have great fear that

we will end up with a piece of legislation that, in fact, will make the situation worse, not better.

Senator DASCHLE. I have some additional questions, but perhaps I can turn to Senator Craig for his questions prior.

Senator CRAIG. I think I am going to be redundant. I apologize for stepping out for a few moments.

I think, Pat, my frustration is when I look generally at the approach you are taking, that I am as concerned as the Senator from Nebraska that I see detections of problems and penalties for violators more than I see an overhaul of the existing system and bringing in place the new science and new technique and new knowledge that I think we simply have to get to.

I know there are rigidities built into this system, and those come from a long history. They come from union insistence. They come from a lot of things. We have to get beyond that.

If you don't bring legislation to us that gets us beyond that and moves us progressively into the 21st century as a partner of industry, then I am going to be very resistant to anything you propose. We have to partnership in this. That is where USDA has shined in the past, not as the big bad cop but as a progressive partner with an industry that is at risk always in the quality of the product it produces and the public acceptance of that product or the public concern about its lack of quality. We all know that.

I guess my question to you is, is that where you are headed, or are we going to see a listing of a lot of ways to detect problems, and ways to level penalties, that don't move us ahead with HACCP; or something modified of that, that brings us to being able to detect risk and high-level risk and corrections and the process to get us to the point, that Dr. Laster has said pretty clearly. If you don't contaminate the carcass or the product, you don't have the problem, plain and simple.

Ms. JENSEN. I sincerely hope and do believe, Mr. Craig, that we are headed in the direction that you have elaborated.

I would like to state again that our ability to move ahead, to set up HACCP and to work on improved science and improved methods doesn't need this legislation. This legislation is filling some gaps in a system. We now currently cannot trace back from the slaughterhouse all the way back to the source. In many cases, we can't trace back.

We want to work with industry and with farmers, producer groups, to fill those gaps so that what we have is a completed package, but we are moving ahead in many of the areas in the ways that you have talked.

Dr. Laster is, I think, one of the best examples for the kind of enthusiasm that we do have at USDA. You can't listen to him testify without knowing that he understands the importance of this issue and of developing these tests. I see our using the tests that he is developing in a HACCP program, in helping us to set guidelines so that we can know at those critical control points if, in fact, we are doing what we are hoping to do in that process and improving the safety of the food.

I do need to stress that what this legislation is about is filling those gaps. We are already moving ahead in other areas of research.

Senator CRAIG. Is the requirement in the proposed legislation that deals with labels, safe handling and cooking, which are already a requirement in USDA regulation, is that part of the gap-filling? The other side of the story, and you know it well, and this administration, to their credit, Secretary Espy, to his credit, began to move in that area. There is another side to the story, and that is that the consumer has to be responsible for their part of the equation once the product gets to them in a safe way.

You already have that regulation. Is this going to be a broader, deeper regulation? Is it to fill gaps that you sense are there, or is it the piling on?

Ms. JENSEN. You might say that this elevates that to the statutory level and sets it as a requirement by statute. We believe so very strongly in that message and in safe handling by the consumer, but this will elevate that into a statutory level.

Senator CRAIG. Thank you, Mr. Chairman.

Senator DASCHLE. Thank you, Senator Craig.

Ms. Jensen, I noted in your testimony that you didn't include any proposal for random testing of meat and poultry products for bacteria levels or pathogen content, but I am told the ground beef purchased for school lunch programs currently undergo random testing for bacteria levels.

Does the Department have any plans in the near future to extend this or any other random testing to all ground beef sold in the United States?

Ms. JENSEN. Mr. Chairman, that could be one of the elements of regulation as we look to setting guidelines. As we develop the science and we have the ability to do those things, that may very well be a logical outgrowth of that.

Senator DASCHLE. So you are pretty indefinite about whether it is going to happen or not?

Ms. JENSEN. I will tell you that I favor, myself, using science to the extent that we can to test, to set guidelines, to know what we have. We have increased our testing of cooked product. We have now a zero tolerance on pathogens for cooked product that goes out of Federal establishments. So we do have a history of using standards and tests on product.

Senator DASCHLE. I know you have a history of it, and obviously in some programs we are already doing it. The question I was asking is, is there a plan to extend the random testing that we already use for school lunch programs to all ground beef sold in the United States?

Ms. JENSEN. Mr. Chairman, I could see that as a logical outgrowth but I don't have a specific regulation in draft form at this time.

Senator DASCHLE. You don't intend to include any reference to that, of course, in the bill? Obviously, if you are this far along in your decision-making process, you don't address it in the bill?

Ms. JENSEN. Mr. Chairman, we don't need that statutory authority to do that.

Senator DASCHLE. You don't need statutory authority, but it isn't happening. You were talking earlier about discretionary and mandatory requirements of the Secretary. He has chosen to use his discretionary authority to make the decision not to have random

testing for all ground beef. I assume there aren't any plans in the near future to reverse that decision, is that correct?

Ms. JENSEN. Mr. Chairman, there have been discussions between the groups that have come to talk to us about that particular issue. I will tell you that they are ongoing. I would encourage Mike Taylor, when he comes on board, to continue that discussion.

Senator DASCHLE. On another issue, how will the proposed traceback provisions affect the average pork, cattle, and sheep producer?

Ms. JENSEN. As I envision this traceback, it would be a record-keeping system which would follow the animal to the slaughter, and that if we found a problem, a pathogen problem, that it would then allow us to know from what producer it came, if that was necessary, if the pathogen were introduced, say, at that point. It would allow us then to indicate to a producer that, in fact, there may be an existing problem, and in this instance there was a problem, so that we could talk with them and have that ability to know where that came from. No producer wants to be sending livestock or poultry into the system if it isn't in good pathogen——

Senator DASCHLE. I guess what I am asking is what kind of an animal identification system will you use to do that, to make that determination?

Ms. JENSEN. We will set up a specific identification program by regulation, but we have made a commitment to the producers that we will incorporate current systems where they exist, and there are several that exist currently, that we will look at those and in the regulatory process will incorporate those where practical and accommodate that so that we aren't layering on them a whole new set of regulations on record-keeping that could be very burdensome to that industry.

Senator DASCHLE. Can you give me an example of a current system that you feel works well that you might adopt in this new regulatory scheme?

Ms. JENSEN. There is an ear tag system, for instance, that the tag would accompany an animal. I see no reason why you couldn't use that particular system.

Senator DASCHLE. What happens if a source of contamination is actually traced back to a farm or ranch? What do you do?

Ms. JENSEN. The legislation in its current draft form would allow the Secretary to prohibit the movement of animals from that farm while the problem existed. It stops at that point. It does not give authority to the Secretary to go onto the farm to dictate farm practices. It would set up a system that would give the producer the information and halt the livestock or poultry from moving into the system until the problem is corrected.

Senator DASCHLE. Last year, we had over three billion pounds of red meat imported into this country. How do you deal with imported meat?

Ms. JENSEN. Imported meat will receive exactly the same treatment as meat in this country receives. We would not put on our own industry a requirement that we would not also insist happen also in imported.

Senator DASCHLE. You are not satisfied with the way imported meat is treated today, are you? Do you not anticipate additional reforms on the inspection and handling of imported meat?

Ms. JENSEN. Mr. Chairman, I anticipate reform in all areas.

Senator DASCHLE. That is what I am asking, Ms. Jensen, if you could be a little more specific as to what you anticipate. That is what this hearing is about, is to give you an opportunity to describe more precisely what we can expect and then have the opportunity to talk about it.

Ms. JENSEN. If I may, Mr. Chairman, I, as you mentioned earlier, have brought with me today Dr. Alex Thierman, who oversees our international services and deals with exactly the issue that you are talking about. I would like him to address that for us.

Senator DASCHLE. Dr. Thierman?

Dr. THIERMAN. Good morning, Mr. Chairman.

As we envision today, Mr. Chairman, as individual specific regulations addressing the level of contamination in meat or the requirements for the movement of animals between States, there would have to be an equivalent in the same for animals or products coming in from overseas.

Senator DASCHLE. They are not equivalent now?

Dr. THIERMAN. They are equivalent now, but as we improve or modify the system at the national level, it would be done automatically at the same time to products coming in so that we don't create an unjustified difference between products.

Senator DASCHLE. So what is new about that, Dr. Thierman?

Dr. THIERMAN. What is new about what, Mr. Chairman?

Senator DASCHLE. I was asking what the reforms will be specifically, what we can anticipate as a result of this bill. You said that there will be a requirement for equivalency, and that as the new regulatory structure comes into place affecting domestic product, the same regulatory implications will affect imported meat as well. That would seem to me to be something that we have done for a long period of time. What is new about the reform that you have just described?

Dr. THIERMAN. I have not described the new reform. I have described it as changes that are made that affect or improve the quality of the pathogen reduction of products and animals domestically, they have to be imposed at the same time on products coming from overseas.

Senator DASCHLE. That is current law, is it not, Dr. Thierman?

Dr. THIERMAN. It is.

Senator DASCHLE. I asked Ms. Jensen if she could give me an explanation, perhaps a more precise illustration of the kind of reforms that we may include in the new bill affecting imported meat. She then said that you were the expert and that you could share with us what those specific reforms are. You have just stated current law.

Are you with that answer telling me that there is really nothing new in this bill that will relate directly to imported meat? Are we not reforming anything? If we are not, then I hope we don't use the word "reform" in describing what it is we are talking about here.

Dr. THIERMAN. Mr. Chairman, for example, you asked the question on traceback. As we implement the regulation on traceback,

we would be modifying the regulations or the requirements that we have on traceback today. It would allow us to traceback imported products or imported animals to a greater degree than what we allow today.

So as the specific implementations are applied to domestic animals and products, they would be simultaneously done on imported animals and products.

Senator DASCHLE. Again, I am not going to belabor this, but I must say, what you are saying is that we are going to continue to try to have equivalency between imported and domestic product and that that is the essence of the bill as it relates to imported product today. I must say, I am just warning you, there is going to be a lot more of this in the weeks and months ahead if that is the best explanation we get once the bill comes.

Ms. Jensen?

Ms. JENSEN. Yes, Mr. Chairman. I would ask Mr. Thierman to spend just a minute on the change that we were discussing and, in fact, is existing in the bill now in its draft form, that has to do with the new definition of "disease" for the purposes of APHIS, which is the agency that he came out of. That is what I was referencing, and there is a change recommended in the law relative to import requirements that Dr. Thierman could address for you.

Senator DASCHLE. I will invite him to do that, but let me just talk one more minute about this equivalency question.

The fact is, you can't be equivalent in all cases between imported and domestic product. Traceback is a much different set of circumstances with imported product than it is here in the United States. So to imply that somehow we can have equivalency, as much as we might like to espouse it and advocate it for a lot of reasons, is simply not practical.

So there is going to have to, by nature, by definition, be a different set of circumstances with the way we treat imported product than there is red meat produced in this country. Is that not the case, Dr. Thierman?

Dr. THIEMAN. Mr. Chairman, I think that we do have, we have to continue to have, equivalency. What you are referring to in a traceback, you may not have the authority to trace back an animal or a product to its original farm of origin in a foreign country, but you do, and we expect to have the authority, just like the Secretary can prevent the movement of an animal out of a farm in the United States, it would prevent the movement of any further products or animals from that country of origin or from that particular source. To the degree that our counterpart in that foreign country collaborates to identify the original source is how far we will have to prevent that movement.

Senator DASCHLE. That is not equivalency. I must say, that whole question of what we do in cases like that are really what I think some of us are looking for.

You will have countless occasions where you will not be able to trace back. There will be no way that you can determine the origin of the product. I think therein lies some of the problem with the way we treat imported product versus domestic product and the attempt at equivalency.

So I think that we have to be a lot more specific and you have to demonstrate to us you are going to be a lot more aggressive than what I have seen this morning. Again, I haven't seen the proposal and I am not going to belabor it any more, but we have to be a lot more comprehensive in our approach to this issue than what you have indicated you are prepared to do this morning.

Ms. Jensen, you were going to ask Dr. Thierman for an explanation.

Ms. JENSEN. I think that what I was talking about was probably not applicable to what your point was about.

Dr. THIERMAN. If I may briefly, Mr. Chairman, the point that Ms. Jensen addressed is the definition of "disease." Currently, we do not have the authority to control or prevent the movement of an animal that is the carrier of a disease that does not cause a clinical disease in those animals.

In the case of *E. coli*, 0157 is a good case, until now, the Secretary does not have the authority to intervene in a case where the agent does not cause disease to animals, and this applies to domestic as well as to imported. It will allow us to prevent the importation of animals even though that particular agent may not cause a clinical disease to those animals.

Senator DASCHLE. Thank you, Dr. Thierman.

Ms. Jensen, let me just ask you a final question. I am concerned that given our lack of legislative progress on USDA reorganization, that we may not see passage of that bill this year. If that does not occur, then the creation of an independent food safety agency within USDA would also be in doubt.

Are you planning to incorporate the creation of an independent food agency in this bill?

Ms. JENSEN. This bill would be consistent with an independent food agency within USDA. There is nothing in this bill that requires it nor would be an impediment to its existence.

Senator DASCHLE. So you don't require an independent food safety agency in the bill itself, the creation of it?

Ms. JENSEN. No, there is no creation of that agency.

Senator DASCHLE. Are you opposed to that?

Ms. JENSEN. No, I am not.

Senator DASCHLE. Then why would you not include it in the bill?

Ms. JENSEN. Because, Mr. Chairman, it is already in the reorganization bill.

Senator DASCHLE. We already know what the status of that legislation is, so why would you not include it in the bill? If you support it there, why wouldn't you support it here?

Ms. JENSEN. I am not saying we wouldn't support it here, I am just saying that currently it isn't in there. When we put a reorganization bill out there, we assumed that that is the bill that is going to pass. However, if it ends up in this bill, we would have exactly the same opinion, which is very supportive of a food safety initiative.

Senator DASCHLE. I must say, I have got very mixed feelings about what I have heard this morning. I guess I am encouraged that we will have a bill by the end of the month, but I am extraordinarily discouraged by the lack of specificity, the lack of any real concrete demonstration of intent to reform. I am going to give you

the benefit of the doubt, Ms. Jensen, but I hope that this bill is a whole lot better than the testimony I have received this morning.

I also would want to point out that it isn't just the Department of Agriculture that is responsible, I think, to a certain extent, for the slow way with which we have confronted this issue. I also understand that there are those outside the Department of Agriculture who would prefer no bill, and I think we have to recognize that it is inside and outside, that we have got to hold those accountable.

There is absolutely no reason why we can't pass legislation this year. To whatever extent possible, I am going to see to it, working with the majority leader, working with the Chairman of this committee, working with the House, that before we close shop at the end of this session, we will have passed a bill. I am prepared to offer my own bill, offer a lot of amendments to this bill, do whatever is necessary to make sure that this reform is indeed real reform in a timely manner.

I appreciate your coming before the committee this morning. With that, the hearing stands adjourned.

[Whereupon, at 10:12 a.m., the subcommittee was adjourned.]

A P P E N D I X I I I

PREPARED STATEMENTS

PATRICIA JENSEN

Mr. Chairman, Members of the subcommittee, and guests. I am pleased to be here this morning to discuss the legislative proposal that the Department of Agriculture is currently preparing to send to Congress for approval. This proposal is just one component of the Secretary's continuing, aggressive efforts to reform the meat and poultry inspection system. The purpose of this legislative proposal is to extend the authority of the Secretary of Agriculture in a number of areas beyond what is currently provided in Federal inspection laws and animal quarantine laws. The additional authorities reflect Secretary Espy's and my commitment to improving food safety from farm-to-table and will provide increased public health protection by reducing foodborne pathogens in meat and poultry products and by improving animal health.

As you know, Mr. Chairman, Secretary Espy recently appointed Mike Taylor of the Food and Drug Administration (FDA) to serve as Administrator of the Food Safety and Inspection Service (FSIS), one of the agencies I oversee. Secretary Espy and I welcome the arrival of Mr. Taylor. He will bring valuable experience with food safety issues, a thorough understanding of the legislative process, a strong consumer orientation, and a commitment to working with all parties concerned with protecting public health. Secretary Espy and I look forward to having him join our team in developing this legislative proposal and in achieving our goals to implement meat and poultry inspection system reforms.

The Department has been developing pathogen reduction legislation for some time. This process has been a multiagency effort, because the safety of the food supply is a responsibility shared by the Animal and Plant Health Inspection Service, the Food Safety and Inspection Service, the Agricultural Marketing Service, the Packers and Stockyards Administration, the Extension Service, and the Food and Drug Administration. It was also essential that, in developing this legislative proposal, full consideration be given to the many concerns and questions raised by stakeholders such as consumer groups, industry and producer representatives, and employee unions. To ensure development of a comprehensive, effective plan, the Department has worked very hard to ensure the participation and interaction of all interests. It is through public input, and the ideas, concerns, and suggestions this generates, that our objectives can be effectively achieved.

In this regard, recently, as the Department approached the conclusion of this process—with a draft proposal near closure—we held a series of meetings with representatives of consumer and industry groups, producers, employee unions, officials of the Food and Drug Administration, and House and Senate staff members to explain the basic elements and objectives of our draft legislative proposal. This series of meetings provided us with new information, and prompted us to reconsider a number of important issues.

I would like to briefly share with you a few of the issues that have been raised and discussed. Consumer representatives, for example made suggestions about the need to set microbial standards. Industry representatives made recommendations on

authority to recall. Producer representatives raised the importance of clarifying the traceback requirements and made suggestions about recordkeeping requirements. The employee unions discussed maintaining principles of the current inspection system in the interest of food safety. The issues raised during these discussions convinced us that the draft proposal needed to be refined.

In addition, all of the groups, including many of the House and Senate Agriculture Committee staff members who attended our Hill briefings, expressed the strong desire to continue working closely with us as we further refine and develop this legislative proposal. Mr. Chairman, we feel that such continued cooperation is essential to the success of this legislative effort. We will be meeting again with consumer, industry, producer, and other representatives to continue working to develop the most comprehensive and effective bill possible.

The concepts of the draft legislative proposal I will discuss today would provide the secretary with additional, essential tools to comprehensively meet our objectives to address the significant public health risks caused by foodborne pathogens in meat and poultry. Such statutory changes will complement the wide range of on-going initiatives we have already instituted under current law to protect public health. These other initiatives include:

- the strict enforcement of zero tolerance policies;
- the implementation of HACCP;
- the mandating of safe cooking and handling labeling; and
- the development of a microbial rapid test for use in plants—which Dr. Laster will testify about today.

The Secretary is authorized by the Federal Meat Inspection Act and the Poultry Products Inspection Act to protect the health of consumers by ensuring that meat and poultry products distributed in commerce are wholesome, not adulterated, and properly marked, labeled, and packaged.

The Department's meat and poultry inspection program has made progress in reducing risks to public health from observable conditions during ante- and post-mortem inspection. New regulatory controls on finished meat and poultry products have been effective in controlling pathogens such as *salmonella* in ready-to-eat products. The National Residue Program, which tests for chemicals and drug residues, has demonstrated declining violation rates for a number of years—in the last 3 years, violative residues have been found in less than $\frac{3}{10}$ of 1 percent of samples analyzed. However, substantial challenges continue to confront us.

The production of meat and poultry products has become increasingly complex. There is an ever increasing variety of raw and processed products with extended shelf life. The technologic changes that made these products possible have contributed to the greater need for scientific research and techniques to determine the origin and path of foodborne illness.

Foodborne illnesses are often caused by microbial pathogens. Pathogenic microbial contamination of meat and poultry products can occur at any point in the farm-to-table continuum.

The Department's legislative proposal will give the Secretary the authority necessary to address food safety concerns at all points on this continuum.

USDA PATHOGEN REDUCTION PROPOSAL

Some elements that we are considering for inclusion in our proposal are:

- pathogen reduction;
- mandatory recall of adulterated or misbranded product
- the ability to trace animals presented for slaughter back to the source of any contamination;
- additional authority to withdraw or refuse inspection;
- authority to impose civil penalties for violation of the inspection laws; and
- a definition of the term "disease" in the animal quarantine laws to enable the Secretary to protect human health.

I would like to briefly discuss each of these elements for the subcommittee's information.

Pathogen Reduction. We are considering that the Secretary, using the best available scientific and technologic data and after evaluating the risks posed to public health and safety, be directed to promulgate regulations to:

- limit the presence of pathogens in livestock and poultry at the time they are presented for slaughter;
- control the presence and growth of pathogens on carcasses and meat and poultry products prepared in any official establishment;
- ensure that all ready-to-eat meat and poultry products prepared in any official establishment are free of foodborne pathogens; and ensure that raw or partially cooked meat and poultry products prepared at any official establishment are labeled with instructions for handling and preparation for consumption.

Scientific studies, some of which are already underway, should provide us with the microbial data and anti-microbial treatments needed to enable us to achieve these statutory objectives.

We intend that meat and poultry products that do not comply with FSIS regulations would be declared adulterated or misbranded. Processors would be given the opportunity to reprocess adulterated products if reprocessing will result in a safe product. If the product is misbranded, processors would be given the opportunity to label it properly. We would give processors this opportunity to prevent unnecessary loss of meat and poultry products only if the reprocessed or relabeled product will not constitute a threat to public health. However, these opportunities would not compromise our efforts to further increase public health protection.

Mandatory Recall. Many have expressed surprise that the Secretary does not already have mandatory recall authority. Perhaps the industry's willingness to recall product voluntarily has contributed to this perception. Although the meat and poultry industries have been very cooperative, we believe that the authority to recall products which pose a threat to human health is the most fundamental authority a Secretary should possess. Voluntary recall implicitly or explicitly involves negotiation with affected industry members. The proposal we are considering would include a mandatory recall provision to supplement the voluntary recall system. We anticipate this authority would be used only when firms refuse to recall products voluntarily.

In addition, under current law the secretary may detain adulterated or misbranded product only for 20 days. The proposal we are considering would authorize the secretary to stop the distribution of adulterated or misbranded product until its proper disposition can be determined.

Traceback. In order to trace animals back to the source of contamination, we are considering a proposal that the Secretary be able to require that animals presented for slaughter be identified so that they can be traced to previous premises where they have been held before slaughter. We may also seek authority to prevent animals not so identified from entering any official slaughtering establishment.

We want the Secretary to be able to require producers and handlers to maintain records to track the purchase and sale of food animals as far back as necessary. These same records could also be an important epidemiological resource. Some producer groups have pointed out to us that they already keep records as part of their quality assurance programs that will be useful to USDA in conducting tracebacks. To the extent that we can rely on these records, we would do so in lieu of imposing duplicative Federal requirements. We also intend to make use of records that we currently require under other USDA programs.

Producer groups have also expressed interest in ensuring that any traceback authority proposed by the Department treat domestic and imported animals equally. Accordingly, our proposal may provide that imported animals are traceable to the point of importation.

Refusal or Withdrawal of Inspection. Federal inspection laws currently give the Secretary the authority to refuse to provide or to withdraw inspection if the applicant or recipient has been convicted of certain violations of law. We are considering proposing that the Secretary be authorized to refuse to provide or to withdraw inspection service for repeated and significant safety violations. Such authority would ensure that operators who are unwilling or unable to correct food safety violations would not be permitted to produce meat or poultry products. Our proposal would maintain the due process protections currently provided in Department proceedings regarding the provision of inspection services.

Civil Penalties. In addition to the new refusal and withdrawal authorities, the Secretary would be provided with new authority to impose civil penalties in circumstances in which other regulatory actions have proved ineffective. Currently, criminal prosecution of cases involving violations of the inspection laws are

sometimes declined by the Department of Justice because of its workload and the highly technical nature of our inspection programs. Effective enforcement of inspection laws would be assured by providing the Secretary with authority to assess civil penalties. Enforcement measures would then range from a written reprimand to fines of not more than \$100,000 per incident per day. The severity of the penalty would reflect the seriousness of the violation. We would provide the right to a hearing before assessing any civil penalty, as well as the opportunity for judicial review.

Defining "Disease" in Animal Quarantine Laws. These proposed statutory changes to the Federal Meat Inspection Act and Poultry Products Inspection Act currently under consideration would greatly enhance the Secretary's ability to protect public health. However, any legislative proposal would be insufficient if it did not also include an expansion of the Secretary's authority under the animal quarantine laws. Current law authorizes the Secretary to regulate the movement of animals and products in interstate and foreign commerce to prevent the spread of communicable animal diseases. The Secretary is not now authorized to take regulatory action to protect public health under the animal quarantine laws unless the disease which is the subject of regulatory action is communicable from one animal to another.

Our recent experience with *salmonella enteritidis*, (SE) a pathogen found in live poultry and eggs, illustrates the limitations of the Secretary of Agriculture's authority to protect against serious threats to public health presented by pathogens in live animals. USDA was able to respond to this outbreak directly (rather than through the intervention of FDA) only because we were able to find that SE had some effect on live poultry and could be transmitted from one animal to another.

Based on this finding, the Secretary was able to implement a successful program to control the movement in commerce of eggs from SE-infected flocks that were implicated in human outbreaks.

We are considering changes to the animal quarantine laws to eliminate this gap in the Secretary's ability to protect human health. Specifically, the term "disease" would be defined to include any infectious and non-infectious disease and any other health-related condition that may be transmitted by livestock or poultry to other animals or humans. This definition will authorize the Secretary to take regulatory action to eliminate pathogens and residues in live animals when such action is necessary to protect the health of other animals or humans.

We are also considering changing a provision that prohibits the importation of ruminants and swine that are infected with disease or have been exposed to infection within 60 days before their exportation to the United States. Our legislative proposal would instead give the Secretary authority to prohibit or restrict importation of infected and exposed animals. Therefore, the Secretary could allow the importation of infected or exposed animals which do not pose a threat to other animals or humans. Without this change, our new definition of "disease" would prohibit the importation of almost all animals into the United States. Other nations might respond by imposing similar restrictions on animals from the United States.

CONCLUSION

Mr. Chairman, and Members of the subcommittee, this concludes my remarks on the new legislative proposal we are currently preparing for Congressional review and approval. I appreciate the opportunity to speak to you today about changes we believe are necessary to strengthen our role in the area of public health. We recognize your commitment to pathogen reduction and to a reformed and modernized inspection program.

We will be meeting again with consumer groups, producer groups, industry groups, employee unions, and House and Senate staff members to continue to refine this proposal.

Mr. Chairman, these efforts will yield a bill that will attract broad support, a bill that will provide for increased public health protection through the reduction of foodborne pathogens in meat and poultry products. This bill plays an important part of the Secretary's and my continuing aggressive efforts to reform the meat and poultry inspection system. I look forward to discussing this with you further.

Thank you. I would be happy to answer your questions and respond to your comments.

DR. DAN LASTER

Mr. Chairman, and Members of the committee, I am pleased to be here today. As you know, Secretary Espy, Acting Assistant Secretary Jensen, and new Food Safety and Inspection Service Administrator Mike Taylor are committed to implementing a science and risk-based food safety and inspection system. As a career USDA Agri-

cultural Research Service scientist and Director of USDA's Meat Animal Research Center, my testimony will be directed toward a critical component of this effort—the development of microbial rapid tests for use in both meat and poultry plants.

Since taking office, Secretary Espy has directed us to accelerate our efforts to develop these tests, which are described in more detail below, and Secretary Espy and Acting Assistant Secretary Jensen recently visited our research facilities in Clay Center, Nebraska. We are well along with the generic bacterial test for beef and pork. We also moving ahead aggressively on a generic test for poultry.

The test for generic bacteria is a first, but very important step in the Department's ongoing efforts to improve sanitation procedures and reduce bacterial contamination for both meat and poultry. Once perfected, the tests for generic bacteria will allow testing of meat and poultry carcasses to monitor the quality control process on a near real-time basis.

Most foodborne pathogens found on carcasses in processing plants, including *salmonella* and *E. coli* 0157:H7, come from fecal contamination. Some level of bacterial contamination is almost unavoidable in the process of converting live animals to food. Our objective at this time is to provide technology and research information to reduce the level of bacterial contamination on meat and poultry as low as reasonably possible. These rapid tests would test for generic bacteria. While it may be true that the statistical correlation between total bacterial levels and pathogens is not always high, it is always positive. Moreover, Agricultural Research Service scientists are also working on practical rapid tests for *E. coli* 0157:H7, *salmonella*, and other specific foodborne pathogens.

USDA scientists have adapted a bacterial test, which is used by the pharmaceutical, cheese and other industries to ensure proper equipment sanitation, to measure bacterial levels on beef and pork carcasses. This bacterial test is a microbial ATP bioluminescence test. (ATP, or adenosine triphosphate, is the form of energy storage in all cells).

In less than 5 minutes, this rapid test will provide an accurate and repeatable method of detecting relatively high levels of generic bacteria on beef and pork carcasses. This 5-minute test is as accurate and repeatable as the current, standard 48-hour plate culture test for estimating relatively high levels of generic bacteria.

These results are based on numerous laboratory studies and measurement of bacterial levels by both the rapid test and the 48-hour plate culture test on over 1,000 beef and over 300 pork carcasses sampled in seven different commercial processing plants. Beef carcasses with no contamination sampled within 45 seconds after hide removal have near zero-levels of bacteria (less than 10) per square centimeter, while carcasses with visible fecal contamination average 100,000 bacteria per square centimeter and ranges from 10,000 to over 10,000,000 bacteria per square centimeter.

While the rapid test cannot accurately predict exact bacterial levels, it can accurately identify carcasses with relatively high levels of bacteria as a result of fecal contamination. Since the test can be done in less than 5 minutes, it could be used to test product and monitor sanitation quality control on a near real-time basis.

At this time, we are continuing in-plant studies on the effectiveness of the rapid test on beef carcasses. We are also conducting additional laboratory studies to address specific questions that need to be answered before this bacterial test is ready for use in a regulatory program or in a company quality control program for beef or pork.

Although progress may seem slow to some, I am confident that we are moving rapidly forward and will have the Rapid Test for generic bacteria ready for use by industry and government regulators in the near future.

The rapid test for generic bacteria will not be a perfect test, nor will it be the perfect answer, but it is a very important step forward in the Secretary's commitment to move towards science-based, risk-based inspection systems. The intervention treatments that are being developed can be used effectively to improve the safety of meat and poultry.

I have seen comments that trimming visible fecal contamination on beef carcasses causes more bacterial contamination than not trimming. I know of no comparative research or national survey data to support such a statement. USDA data indicates that trimming and washing will substantially reduce bacterial contamination over washing with tap water only.

While we are not involved in the in-plant studies with hot water and bacterial agents, we are confident that proper washing with hot (180° F.) water rather than tap water can substantially reduce both total bacteria levels and safoodborne pathogens. To replace trimming and washing with hot water washing or bacterial agents, however, would require the use of a standard, effective carcass washer in all processing plants.

More importantly, regardless of whether fecal contamination is removed by trimming and washing with tap water, washing with hot water, or trimming and washing with hot water, there is no way to assure the quality control process is working properly to minimize bacterial contamination unless some type of rapid bacterial test is used. The rapid test that USDA is developing will provide this essential tool to the meat and poultry food safety inspection systems.

Based on my direct contact with leaders of the meat and poultry processing industries, these industries are very willing to implement new technologies to help improve the safety of their product.

As a career USDA employee, my job is research. I am confident, however, that Secretary Espy will move forward decisively and vigorously as soon as we have scientifically sound research information to document these bacterial tests and the intervention treatments that are being developed can be used effectively to improve the safety of meat and poultry.

Mr. Chairman, that concludes my statement. I would be happy to answer any questions.



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